NEVADA STATE
BOARD OF PHARMACY

BOARD MEETING

October 14-15, 2026

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

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

Please do not remove the book from the meeting room.

JOE LOMBARDO
Governor

DR. KRISTOPHER SANCHEZ
Director

PERRY FAIGIN
NIKKI HAAG
MARCEL F. SCHAERER
Deputy Directors

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA

DEPARTMENT OF BUSINESS AND INDUSTRY
OFFICE OF NEVADA BOARDS, COMMISSIONS AND COUNCILS STANDARDS
STATE OF NEVADA BOARD OF PHARMACY

Date Posted: September 24, 2026

AGENDA

◈ PUBLIC NOTICE ◈

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, October 14, 2026, at 9:00 am. The meeting will continue Thursday, October 15, 2026, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

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

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

Please Note:

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

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

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

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

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

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

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

◈ CONSENT AGENDA ◈

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

3. Approval of the September 2-3, 2026, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

4. 4.1 Applications for Out-of-State Medical Products Provider License (NAC 639.6944) – Non-Appearance (**FOR POSSIBLE ACTION)**

   A. ForMotion Clinic – Houston, TX
   B. Milkmoms, Inc – Andover, MN
   C. Mountain West Medical Supply LLC – Blanding, UT
   D. Serenity Medical Supply – Freehold, NJ

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

   Background Check Not Required by Law.

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

   E. Medline Industries, LP – Aurora, CO
   F. Medline Industries, LP – Gresham, OR
   G. Medline Industries, LP – Lathrop, CA
   H. Medline Industries, LP – Tracy, CA

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

I. Optum Specialty Services, LLC – Etna, OH

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

J. ArriVent BioPharma, Inc – Gaithersburg, MD
K. Belite Bio Holdings Corp – San Diego, CA

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

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

L. A2A Intergrated Logistics, Inc – Fayetteville, NC
M. BioRidge Pharma, LLC – Florham Park, NJ
N. Independent Pharmaceutical, LLC – West Chester, OH

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

O. Avive Solutions, Inc – Brisbane, CA
P. Beckman Coulter, Inc – Miami, FL
Q. BioFire Diagnostics, LLC – Salt Lake City, UT
R. BioFire Diagnostics, LLC – Salt Lake City, UT
S. Blue Heron Pharmaceuticals, LLC – New Port Richey, FL
T. DePuy Synthes Products, Inc – West Palm Beach, FL
U. Fisher & Paykel Healthcare, Inc – Perris, CA
V. Kanchan Healthcare, Inc – Parsippany, NJ
W. Luria Therapeutics, LLC – Pleasant Prairie, WI
X. Mados, LLC – Boston, MA
Y. Medivant Healthcare – Chandler, AZ
Z. Noramco LLC – Wilmington, DE
AA. Nuvalent, Inc – Cambridge, MA
BB. Ortho Organizers, Inc – Savannah, GA
CC. Pangea Pharmaceuticals, LLC – Brielle, NJ
DD. SteriMax USA, Inc – Mountainside, NJ
EE. Validus Pharmaceuticals, LLC – East Brunswick, NJ

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

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

FF. BioFire Diagnostics, LLC – Salt Lake City, UT
GG. GC Biopharma USA, Inc – Teaneck, NJ

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

HH. 1 Click Logistics – Sparks, NV

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

II. AHCS Patient Care Pharmacy – Las Vegas, NV
JJ. ER of Southern Highlands – Las Vegas, NV
KK. Kaiser Permanente Fifth Street Pharmacy – Reno, NV

4.4 Applications for Out-of-State Pharmacy License for a Pharmacy Intending to Engage in Compounding (NRS 639.2328) – Non-Appearance **(FOR POSSIBLE ACTION)**

LL. Medicap Compounding Center – Coralville, IA
MM. PharmaLogic Cincinnati, LLC – Cincinnati, OH
NN. The Pharmacy Place – Peacetree City, GA

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

OO. Amber Specialty Pharmacy – Omaha, NE
PP. Hy-Vee Pharmacy Solutions – Omaha, NE
QQ. Baton Rouge General Compounding Pharmacy – Baton Rouge, LA
RR. PantherRx Specialty Pharmacy – Collierville, TN
SS. PantherRx Specialty Pharmacy – Coraopolis, PA
TT. PantherRx Specialty Pharmacy – Pittsburgh, PA
UU. Walgreens Specialty Pharmacy #15987 – Sacramento, CA

4.6 Application for Ambulatory Surgery Center License (NAC 639.4992) – Non- Appearance **(FOR POSSIBLE ACTION)**

VV. Pecos Surgery Center – Las Vegas, NV

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

WW. Kreshmimir Rogina

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

4.9 Application for Nevada Warehouse (NAC 639.622) – Non- Appearance **(FOR POSSIBLE ACTION)**

◈ REGULAR AGENDA ◈

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

A.	CVS Pharmacy #9168	(24-010-PH-N)
B.	Marilou Reyes	(24-010-RPH-N)
C.	Quality Compounding Rx of America	(25-253-PH-S)
D.	David Snipper	(25-382-CS-S)
E.	Las Vegas Community Pharmacy	(24-133-PH-S)
F.	Natalie Nguyen	(24-133-RPH-S)
G.	Ali Macintosh	(24-133-PT-S)
H.	Hisbay Ali	(24-444-CS-S)
I.	US Pharmacy	(25-175-PH-S)
J.	Fernesser Tracey	(25-175-RPH-S)
K.	American Wellness Pharmacy	(25-464-PH-S)
L.	James Barber	(25-464-RPH-S)
M.	Jayzle Joy Boyd Justice	(26-137-RPH-S)
N.	Abolfazl Hosseinpour	(26-139-RPH-S)
O.	Revive Rx	(24-482-PH-B-S)
P.	Strive Pharmacy	(24-482-PH-C-S)
Q.	Mikayla Strief	(24-482-CS-A-S)
R.	Justin Spangler	(24-482-CS-B-S)
S.	Daniel Inglish	(24-482-CS-C-S)
T.	Mary Miller-Wilson	(24-482-CS-D-S)
U.	Mark Bernardi	(24-482-CS-E-S)
V.	Tiana Hubbard	(24-482-CS-F-S)
W.	Summerlin Hospital Medical Center Pharmacy	(25-209-PH-S)
X.	Aurelia Hurtada-Sadowski	(25-209-RPH-S)
Y.	Justin Mansfield	(25-447-CS-S)
Z.	Vita Pharmacy 2	(26-344-PH-S)

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

A.	David Lindberg	(24-482-A-S)

7. Discussion and possible action to amend Stipulation and Order entered in Case Nos. 24-289-PH-S and 24-289-RPH-A-S pursuant to NRS 622A.390. **(FOR POSSIBLE ACTION)**

A.	Laughlin Pharmacy & Wellness Center	(24-289-PH-S)

B. Youjin Seo (24-289-RPH-A-S)

8. Applications for Nevada Medical Products Provider License (NAC 639.6942) – Appearance (**FOR POSSIBLE ACTION)**

   A. Alliance Medical Equipment – North Las Vegas, NV
   B. Hudson Medical Co LLC – Henderson, NV
   C. Strive Medical LLC – Las Vegas, NV
   D. Tag 2 Collaboration LLC – Las Vegas, NV

9. Applications for Nevada Pharmacy License (NRS 639.230) – Appearance **(FOR POSSIBLE ACTION)**

   A. Cur8 Pharmacy – Henderson, NV
   B. DOLCRX – Las Vegas, NV
   C. Meta Pharmacy Services – Las Vegas, NV
   D. Quality Compounding Rx of America – Las Vegas, NV
   E. Silver State Rx LLC – North Las Vegas, NV
   F. Valley Specialty Pharmacy – Las Vegas, NV

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

    A. LillyDirect Pharmacy, LLC – Indianapolis, IN

11. Application for Nevada Outsourcing Facility (NRS 639.100) – Appearance **(FOR POSSIBLE ACTION)**

    A. Bespoke Pharmaceuticals, LLC – Las Vegas, NV

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

    A. Nephron Pharmaceuticals – West Columbia, SC – Background Check Not Required by Law
    B. Xttrium Laboratories, Inc – Glenview, IL – Background Check Not Required by Law

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

    A. Knoa Pharma, LLC – Stamford, CT – Background Check Not Required by Law
    B. Knoa Pharmaceuticals, LLC – Wilson, NC – Background Check Not Required by Law

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

    A. Paolo Nunez Blanquisel

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

    A. Jaywant Parmar - Practitioner

16. Review of Regulations as required by Executive Order 2026-003 **(FOR POSSIBLE ACTION)**

    A. In accordance with Executive Order 2026-003, the Board will:
        i. Solicit from key industry stakeholders recommendations regarding regulations that should be streamlined, clarified, or removed;
        ii. Undertake a comprehensive review of the regulations subject to its enforcement; and
        iii. Identify other regulatory changes the Board determines worth of consideration.

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

18. Executive Secretary Report:

    A. Financial Report
    B. Issuance of Temporary Licenses and Registrations
    C. Change of Address Business List
    D. Meetings with Other Health Care Regulatory Boards
    E. Licensing Activities Report
    F. Citations & Fines issued pursuant to NRS 632.2895
    G. Legislative update
    H. 2027 NVBOP Yearly Calendar

19. Date and Location of Next Scheduled Board Meeting:

    December 2-3, 2026 – Las Vegas, NV

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

21. Adjournment

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

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

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

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

1

2

3

NEVADA STATE BOARD OF PHARMACY

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

(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

BOARD MEETING MINUTES

September 2-3, 2026

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, September 2, 2026, at 9:00 am. The meeting will continue Thursday, September 3, 2026, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

Hyatt Place
1790 E Plumb Ln
Reno, NV

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

Board Members Present:

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

Board Staff Present:

David Wuest	Yenh Long	Amy Steelman	Jessette Phaynarikone
Laura Tucker	Skylar Young	Todd Weiss	Darlene Nases
Mui Lee	Ryan Miller	Patrick Conmay	William Kuykendall
Brett Kandt			

Call to Order and Roll Call – Establishment of Quorum

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

Public Comment on September 2, 2026, 9:00 AM

There was no public comment.

3. Approval of July 15-16, 2026, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

Jade Jacobo recused herself since she was not here for the July 2026 Board Meeting.

Board Action:

Motion: Chanyis Taylor moved to approve July 15, 2026, Board Meeting Minutes.

Second: Jade Jacobo

Action: Motion passed (Jacobo recused).

Board Action:

Motion: Adam Porath moved to approve July 16, 2026, Board Meeting Minutes.

Second: Krystal Freitas

Action: Motion passed (Jacobo recused).

◈ CONSENT AGENDA ◈

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

4. 4.1 Applications for Out-of-State Medical Products Provider License (NAC 639.6944)

- Non-Appearance (**FOR POSSIBLE ACTION)**

A. Corner Home Medical – Dilworth, MN
B. Diabetic Equipment and Supplies – Johnston, IA
C. NextGen Medical Supplies – Delray Beach, FL
D. OrthoKinetix – Riverside, CA
E. Professional Medical Corp – Seattle, WA
F. Quickfill Rx Inc – Tarzana, CA

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

Background Check Not Required by Law.

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

G. Dyne Therapeutics Inc – Waltham, MA

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

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

H. Appellis Pharmaceuticals Inc – Waltham, PA
I. Cardinal Health 200 LLC – Champlin, MN
J. Mineralys Therapeutics Inc – Boston, MA
K. Novavax Inc – Gaithersburg, MD
L. QuidelOrtho Sales Company LLC – Memphis, TN

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

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

M. American Pharmaceutical Distributors – Waterford, MI
N. Golden State Medical Supply Inc – Camarillo, CA
O. Golden State Medical Supply Inc – Camarillo, CA

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

P. Almatica Pharma LLC – Morristown, NJ
Q. Aroa Biosurgery Incorporated – San Diego, CA
R. bioMerieux Inc – Durham, NC
S. bioMerieux Inc – Hazelwood, MO
T. Dynavax Technologies Corporation – Emeryville, CA
U. Esai Inc – Nutley, NJ
V. Gamida Cell Inc – Naples, FL
W. Neurent Medical Inc – Braintree, MA
X. Praxis Packaging Solutions – Lakeland, FL
Y. Rayner Surgical Inc – Memphis, TN
Z. Shine Spect USA LLC – North Billerica, MA
AA. Spineology Inc – Saint Paul, MN
BB. USWM CT LLC – Philadelphia, PA
CC. Vero Biotech Inc – Livingston, TN
DD. Zoll Medical Corporation – Wilmington, MA

DRAFT

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

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

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

EE. 1 Click Logistics – Sparks, NV
FF. Global Direct Rx LLC – Park City, UT

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

GG. Albertsons Pharmacy #0195 – Las Vegas, NV
HH. Kaiser Permanente Del Monte Pharmacy – Reno, NV

4.4 Application for Out-of-State Pharmacy License for a Pharmacy Intending to Engage in Compounding (NRS 639.2328) – Non-Appearance **(FOR POSSIBLE ACTION)**

II. Eden – Albuquerque, NM
JJ. Emerald Compounding Pharmacy – Tampa, FL
KK. Esatto Pharma – Chandler, AZ
LL. FarmaKeio AR – Conway, AR
MM. FarmaKeio – Richardson, TX
NN. Formulation Compounding Center – Lewisville, TX
OO. Hephaestus Pharmaceuticals LLC – Doral, FL
PP. Jungle Jim's Pharmacy – Fairfield, OH
QQ. Nutrishare LLC – Phoenix, AZ
RR. Premium Health Care Pharmacy – Miami, FL
SS. Prescription Center – Idaho Falls, ID
TT. Rush Pharmacy TX01 – Plano, TX
UU. Southend Pharmacy – Houston, TX
VV. Tower Medic Pharmacy Inc – Fort Worth, TX
WW. Vault Pharmaceuticals LLC – Brooksville, FL

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

XX. All Discount Pharmacy LLC – Delray Beach, FL
YY. Amazon Pharmacy #016 – Richmond, CA
ZZ. Blue Rx – Frisco, TX
AAA. Carepoint Pharmacy – Schaumburg, IL

DRAFT

BBB. Central Care Pharmacy/GHST Rx Inc – Encino, CA
CCC. divvyDOSE – Moline, IL
DDD. HomeMed Pharmacy – Carmel, IN
EEE. Med Stork Rx – Garland, TX
FFF. Neighborhood LTC Pharmacy – Phoenix, AZ
GGG. PhilRx – Scottsdale, AZ
HHH. Restore Pharma LLC – Tampa, FL
III. Senderra Rx Partners LLC – Morrisville, NC
JJJ. TheraGenix Pharmacy Inc – Maynard, MA
KKK. Vials – Tomball, TX

4.6 Application for Nevada Ambulatory Surgery Center License (NAC 639.4992) – Non- Appearance **(FOR POSSIBLE ACTION)**

LLL. Digestive Health Center – Reno, NV
MMM. Painted Mirage Surgery Center LLC – Las Vegas, NV

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

4.8 Application for Nevada Warehouse (NAC 639.622) – Non- Appearance **(FOR POSSIBLE ACTION)**

NNN. New Deantronics Ltd – Sparks, NV

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

OOO. Wesley Pharmaceuticals – Orlando, FL

Adam Porath recused himself from Agenda Item# 4HH.

President Park removed Agenda Item #4UU, and Dave Wuest, Executive Secretary for the Nevada Board of Pharmacy, clarified that the business will appear before the Board on Thursday.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve Consent Agenda with exception to Agenda Items# 4UU and 4HH.

Second: Chanyis Taylor

DRAFT

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to approve Consent Agenda Item# 4HH.

Second: Chanyis Taylor

Action: Motion passed (Porath recused).

◈ REGULAR AGENDA ◈

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

E. Vladimir Mityushin (25-279-RPH-N)

Vladimir Mityushin was present.

Adam Porath disclosed that he knows Mr. Mityushin from his employment at Renown, but he can participate in this matter fairly and without bias.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy prosecuted the case against Vladimir Mityushin, alleging that Respondent Mityushin committed errors in compounding sterile products.

The proposed stipulated penalties for Valdimir Mityushin, Certificate of Registration No. 17247, are the following: 1) Certificate of Registration No. 17247 is suspended for a period of one year. The suspension is stayed and is placed on probation subject to the following conditions: 1) Respondent fined $1,500 for the violations; 2) Respondent assessed $1,000 in attorney's fees and costs; 3) Respondent shall not engage in compounding sterile drug products until completing a minimum of twenty (20) hours of continuing education specifically related to sterile compounding in compliance with chapter 797 of the United States Pharmacopeia - National Formulary and providing completion to Board staff; and 4) Respondent shall comply with all federal and state statutes and regulations regarding controlled substances, dangerous drugs, and the practice of pharmacy, shall have no additional administrative charges filed by the Board, and shall have no action taken that would be reportable.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve Stipulation and Order for Vladimir Mityushin as presented by Mr. Kandt.

Second: Chanyis Taylor

Action: Passed unanimously.

F. Bespoke Pharmaceuticals, LLC (25-385-PH-S)

Luis Lanz, Esq., was present.

Jade Jacobo knows Luis Lanz from her employment with Walgreens, but she can participate in this matter fairly and without bias.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, alleged that when applying for licensure, Bespoke Pharmaceuticals failed to ensure that all information regarding the managers and/or persons beneficially interested in Bespoke was complete and accurate.

The proposed stipulated penalties for Bespoke Pharmaceuticals, LCC, Pharmacy License No. PH04719, are the following: 1) Respondent is fined $10,000 for the violations; 2) Respondent assessed $5,000 in attorney fees and costs; and 3) Neither Yury Gampel nor Michael Tiraturian will have any involvement in management of Bespoke Pharmaceuticals, including any future company names or DBAs, or involvement in the facility's dad-to-day operations.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order for Bespoke Pharmaceuticals, LLC, as presented by Mr. Kandt.

Second: Krystal Freitas

Action: Passed unanimously.

G. Dana Marks (25-408-CS-N)

Lyn Beggs, Esq., was present.

President Park recused herself from this matter due to her previous employment. Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the matter, alleging that by surrendering his NSBME License No. 9358 to practice medicine and his DEA Registration No. BM5206405 for cause, Respondent no longer qualifies for registration to dispense controlled substances under federal or state law and his Certificate of Registration No. CS09880 is subject to revocation.

DRAFT

The proposed stipulated penalties for Dana Marks, Certificate of Registration No. CS09880, are the following: 1) Certificate of Registration No. CS09880 is revoked; 2) Respondent may not possess (except pursuant to the lawful order of a practitioner), administer, prescribe or dispense a controlled substance until he has petitioned the Board for reinstatement pursuant to NRS 639.257 and the Board reinstates his certificate of registration. 3) Respondent may not petition for reinstatement of his certificate of registration for a period of one year from the effective date of the order; 4) If Respondent seeks reinstatement of this certificate, or applies for any other certificate, license, or permit with the Board, he must appear before the Board. During that appearance, he will be required to answer questions, provide testimony regarding his application, demonstrate compliance with this Order, and address the facts and circumstances related to this matter; and 5) Respondent is assessed $1,000 in attorney's fees and costs.

Board discussion ensued.

Board Action:

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

Second: Adam Porath

Action: Motion passed (Park recused).

M. Sierra Center for Foot Surgery (25-181-PH-N)

Keith Ketola, Esq., was present.

Laura Tucker, Senior General Counsel for the Nevada Board of Pharmacy, alleged that, Sierra Center for Foot Surgery, an ambulatory surgical center, is responsible for the actions of its employee or contracted employee, who failed to visit the surgery center at least once a month to perform required evaluations and compliance duties during the relevant period as required by Nevada law.

Dave Wuest, Executive Secretary, and Ms. Tucker clarified that the other respondent in 5N will be heard at a future Board Meeting.

The proposed stipulated penalties for Sierra Center for Foot Surgery, License No. ASC02426, are the following: 1) Respondent fined $2,500 for the violations; and 2) Respondent assessed $500 in attorney's fees and costs, each due within six months of the effective date of the Order.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Stipulation and Order for Sierra Center for Foot Surgery as presented by Ms. Tucker.

Second: Adam Porath

Action: Passed unanimously.

O.	Empower Pharma	(25-230-WH-A-S)
P.	Empower Pharma	(25-230-OU-A-S)
Q.	Empower Pharmacy	(25-292-PH-O)
R.	Empower Pharma	(25-292-OU-O)

Lyn Beggs, Esq., was present.

Jade Jacobo recused herself from these matters due to her previous employment with Empower.

Laura Tucker, Senior General Counsel for the Nevada Board of Pharmacy, in Case Nos. 25-230-WH-A-S and 25-230-OU-A-S, alleged that Empower shipped dangerous drugs to persons without authority to store or possess those drugs and shipped drugs that were not bona fide transactions. In Case Nos. 25-292-PH-O and 25-292-OU-O, Empower dispensed compounded drugs that were essentially copies of commercially available drug products and failed to document a shortage of said commercially available products and/or failed to document a specific patient need for compounded drug variation thereof.

The proposed stipulated penalties to resolve both cases for Empower Pharma, License No. WH02264, Empower Pharma, License No. OU00033, and Empower Pharmacy, License No. PH03016, are the following: 1) Respondent collectively fined $20,000 for the violations; and 2) Respondent collectively assessed $2,000 in attorney's fees and costs.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Stipulation and Order for Empower Pharma (License Nos. WH02264 and OU00033) and Empower Pharmacy (License No. PH03016) as presented by Ms. Tucker.

Second: Chanyis Taylor

Action: Passed unanimously.

C. Gemma Thomson (22-542-CS-N)

Gemma Thomson was present.

Amy Steelman, General Counsel for the Nevada Board of Pharmacy, took a recess to confer with Ms. Thomson regarding this matter.

Ms. Steelman withdrew the Order to Show Cause against Ms. Thomson.

I. Eric Lawrence (26-255-RPH-S)

Eric Lawrence and Lyn Beggs, Esq., were present.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that Respondent diverted a controlled substance from his employment at CVS Pharmacy #16854 for personal use.

Mr. Kandt stated that Respondent Lawrence, in his Answer and Notice of Defense, admitted the first five paragraphs of the Accusation, which contain the factual allegations.

Ms. Beggs said there is no dispute against the factual allegations.

Mr. Kandt and Ms. Beggs made their opening statements.

Board discussion ensued as to the finding of guilt on the five counts.

Board Action:

Motion: Jade Jacobo moved to make Findings of Fact consistent with paragraphs 1-5 of the Accusation.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to make Conclusions of Law consistent with paragraphs 6-12 of the Accusation and remove any reference of 42 U.S.C. § 12210.

Second: Adam Porath

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to find Respondent Lawrence guilty of Counts One-Five and remove any reference of 42 U.S.C. § 12210.

Second: Chanyis Taylor

Action: Passed unanimously.

Mark Chase, Executive Director for Nevada Professionals Health Programs, provided his evaluation results for Mr. Lawrence.

Board discussion ensued regarding circumstances of the diversion.

Mr. Kandt requested the Memorandum of Costs and Fees of $869.57 be entered as Exhibit 1.

President Park admitted as Exhibit 1.

Board discussion ensued regarding the penalties for Mr. Lawrence.

Board Action:

Motion: Jade Jacobo moved to revoke Certificate of Registration No. 20626 effective immediately, and the respondent cannot petition for reinstatement for a period of three years from the effective date of the Order.

Second: Richard Tomasso

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to assess attorney fees and costs in the amount of $869.57 which were reasonable, necessary, and actually incurred, payable within 30 days of the effective date of the Order.

Second: Anna Carr

Action: Passed unanimously.

Board Action:

DRAFT

Motion: Jade Jacobo moved to fine Eric Lawrence in the amount of $3,000 payable within six months from the effective date of the Order.

Second: Anna Carr

Action: Passed unanimously.

6. Discussion and possible action to amend the Findings of Fact, Conclusions of Law and Order entered in Case No. 25-031-RPH-N in compliance with Order Granting in Part and Denying in Part Petition for Judicial Review in Second J.D. Case No. CV25-02752 (**FOR POSSIBLE ACTION)**

A. Bernard Brooks

Randy Stephenson, Esq., and Bernard Brooks were present.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, explained that upon Respondent's petition for judicial review and in compliance with the District Court's Order Granting in Part and Denying in Part Petition for Judicial Review entered in Second J.D. Case No. CV25-02752, the Board should enter an amended order.

Board Action:

Motion: Jade Jacobo moved to amend the Findings of Fact, Conclusions of Law and Order to conform with the findings of the Judicial Review in the Second Judicial District Court Order.

Second: Adam Porath

Action: Passed unanimously.

The Board and counsel discussed that Mr. Brooks has been compliant with his treatment, and the date of probation should start from the date of the original order, October 16, 2025, with an extension of payment of the fine and attorney fees and costs for one year. Additionally, Mr. Brooks requested the Board's approval to be the managing pharmacist at Sierra Family Pharmacy.

Dave, Wuest, Executive Secretary, explained that Mr. Brooks evaluator/practitioner Bryan Dinerman does not meet the qualification criteria set by the Board but that the practice he was associated with had other evaluators/practitioners that met those criteria.

The Board questioned Mr. Brooks.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to amend the original Order: 1) Certificate of Registration No. 20571 is on probation for a period of three years from October 16, 2025; 2) Respondent fined $5000 for the violations to be payable a year from the effective date of this amended order; 3) Respondent assessed $6,656.06 in attorney's fees and costs to be payable a year from the effective date of this amended order; 4) Respondent must participate in a PRN or equivalent program for the term of his probation where the therapist meets the Board criteria as his evaluator; 5) Evaluator provides quarterly reports to Board staff; and 6) Respondent approved to be managing pharmacist for his current employer (Sierra Family Pharmacy).

Second: Krystal Freitas

Action: Passed unanimously.

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

C. Sahara Pharmacy – Las Vegas, NV

Bilal Mahmood (New Owner), Aamir Iqbal (Pharmacy Manager for the Non-clinical roles of the Pharmacy), Waseem Sarwar (Current Owner), and Khanh Dinh (Managing Pharmacist) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the change of ownership for Sahara Pharmacy.

Second: Adam Porath

Action: Passed unanimously.

7. Application for Nevada Medical Products Provider License (NAC 639.6942) – Appearance (**FOR POSSIBLE ACTION)**

A. Anything Medical – Las Vegas, NV

DRAFT

Melissa Dietz (Administrator and Owner), John Binder (Managing Partner and General Manager), and Craig Perry, Esq., were present.

Mr. Perry has sent an amended application with the removal of the following MDEG products: life-sustaining equipment and parenteral and enteral equipment.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Skylar Young, Nevada Board of Pharmacy Regulatory Compliance Officer, commented that amending the first page of the amended application to reflect John Binder as the emergency contact and resubmitting to Board staff would be satisfactory.

Board Action:

Motion: Adam Porath moved to approve Nevada Medical Products Provider License for Anything Medical pending favorable inspection.

Second: Jade Jacobo

Action: Passed unanimously.

B. Hudson Medical Co LLC – Henderson, NV

Melissa Hudson (Owner) and Suzanna Hicks (Administrator) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

This application was tabled.

C. Medical Wig Supply – Las Vegas, NV

Nikki Rachal (Owner) was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

This application was tabled.

D. Vitality Medical Supplies – Las Vegas, NV

Ryan Yardley (Owner and Administrator) and Sandy Friday (Billing and Credentialer)

DRAFT

were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

This application was tabled.

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

B. Vitality Medical Supplies LLC – Las Vegas, NV – Background Check completed in compliance with NRS 639.500

Ryan Yardley (Owner and Administrator) and Sandy Friday (Billing and Credentialer) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

This application was tabled.

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

A. AZ Care Pharmacy LLC – Las Vegas, NV – Background Check completed in compliance with NRS 639.500

Kardam Panjabi (Owner) was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve Nevada Wholesaler License for AZ Care Pharmacy LLC pending favorable inspection.

Second: Jade Jacobo

Action: Passed unanimously.

DRAFT

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

A. APRX LLC – Las Vegas, NV

Sylvia Durante (Owner) and Wayne Veiock (Managing Pharmacist) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve Nevada Pharmacy License for APRX LLC pending favorable inspection and with the condition that they must notify the Board if they decide to do non-sterile compounding.

Second: Anna Carr

Action: Passed unanimously.

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

A. Chenelle Carter

Chanelle Carter was present.

Jade Jacobo stated that this application is with her current employer Walgreens, but she can participate in this matter fairly and without bias.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Chanyis Taylor moved to approve the Pharmaceutical Technician in Training registration for Chanelle Carter.

Second: Krystal Freitas

Action: Passed unanimously.

Public comment on July 15, 2026, at 3:38 PM

DRAFT

There was no public comment.

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

Board Members Present:

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

Board Staff Present:

David Wuest	Yenh Long	Amy Steelman	Jessette Phaynarikone
Laura Tucker	Skylar Young	Todd Weiss	Darlene Nases
Mui Lee	Ryan Miller	Patrick Conmay	William Kuykendall
Brett Kandt			

Call to Order and Roll Call – Establishment of Quorum

President Park performed the roll call. Board members were present except Jade Jacobo as she will be attending later, and a quorum was established.

Public comment at July 16, 2026, at 9:00 AM:

There was no public comment.

◈ WORKSHOP ◈

Thursday, September 3, 2026 – 9:00 am

17. Notice of Proposed Regulation Workshop Pursuant to NRS 233B.061(2)

B. Amendment to Nevada Administrative Code (NAC) 639. The proposed amendment clarifies the use of digital identify verification and use of real-time, stop sale system related to products that is a precursor to methamphetamine by a pharmacy and other matters properly relating thereto.

David Wuest, Executive Secretary for the Nevada Board of Pharmacy, presented the proposed regulation workshop to the Board.

President Park opened the floor for public comment.

The following person(s) offered public comment:

Carlos Gutierrez, Consumer Healthcare Products Association.

Elizabeth McMenanim, Retail Association of Nevada.

President Park closed the period for public comment.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the proposed amendment to Nevada Administrative Code (NAC) 639 as presented by Mr. Wuest.

Second: Adam Porath

Action: Passed unanimously.

A. Amendment to Nevada Administrative Code (NAC) 639. The proposed amendments relate to the adoption of a fee for the integration of the records of patients in the database of the program established pursuant to NRS 453.162 with the electronic health records of practitioners.

David Wuest, Executive Secretary for the Nevada Board of Pharmacy, presented the proposed regulation workshop to the Board.

President Park opened the floor for public comment.

Jade Jacobo was present at 9:21AM.

The following person(s) offered public comment:

Ken Kunke, Nevada Pharmacy Alliance.

Elizabeth McMenanim, Retail Association of Nevada.

President Park closed the period for public comment.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve Amendment to Nevada Administrative Code (NAC) 639 with amendment to indicate that this regulation would only be implemented in the absence of grant funding and to include all practitioner types in the controlled substance distribution chain with the exception of pharmaceutical technicians.

Second: Jade Jacobo

Action: Passed unanimously.

Richard Tomasso was excused from the meeting at 10:03AM.

10. Application for Nevada Outsourcing Facility (NRS 639.100) – Appearance

A. Bespoke Pharmaceuticals LLC – Las Vegas, NV

Irina Gampel (Owner), Fadi Abdel (Chief Development and Operations Officer), Magdalena Cybulska (Managing Pharmacist), Luiz Lanz, Esq. (Counsel), and Khoi Vu (Director Manufacturing of Operations) were present.

President Park knows Ms. Cybulska and Mr. Vu from her time at Roseman University, but she can participate in this matter fairly and without bias.

Chanyis Taylor knows Mr. Vu from his time at Roseman University, but she can participate in this matter fairly and without bias.

President Park wants all the owners present regarding this application on video via Zoom or in-person.

This application was tabled.

11. Application for Out-of-State Outsourcing Facility (NRS 639.100) – Appearance

A. Bravado Pharmaceuticals LLC – Lutz, FL

Brian McMilan (President and CEO), Shannon Kennedy (Vice President, Chief Security Officer, and Head of Quality), and Aynas Rana (Managing Pharmacist) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Aynas Rana's designation as managing pharmacist has not yet been updated with the Board. Additionally, the sterile compounding questionnaire must be completed, as they attested that sterile compounding activities will be performed.

The application was tabled.

DRAFT

12. Application for Out-of-State Wholesaler License (NRS 639.233) – Appearance –

A. Oxus America Inc – Orion Township, MI – Background Check Not Required by Law

Ryan Lenarcic (Quality and Regulatory Affairs Manager), Mark McAndrew (Counsel), and Gary Abusamra (CEO) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve Out-of-State Wholesaler License for Oxus America Inc.

Second: Adam Porath

Action: Passed unanimously (Tomasso excused).

14. Application for Pharmacist Registration by Reciprocation (NRS 639.134) – Appearance

A. Richard Korb

Richard Korb was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Chanyis Taylor moved to approve Pharmacist Registration by Reciprocation for Richard Korb.

Second: Adam Porath

Action: Passed unanimously (Tomasso excused).

Mr. Korb needs to contact Board staff to fill out the form to do remote work.

16. Applications for Controlled Substance Registration (NRS 453.226) – Appearance

A. Nikesh Seth – APRN

DRAFT

Nikesh Seth was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve Controlled Substance Registration for Nikesh Seth for Schedules II-V.

Second: Anna Carr

Action: Passed unanimously (Tomasso excused).

B. Samuel Jerideau – Practitioner

Samuel Jerideau was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve Controlled Substance Registration for Samuel Jerideau for Schedules II-V.

Second: Adam Porath

Action: Passed unanimously (Tomasso excused).

C. Stuart Feldman – Practitioner

Stuart Felderman was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve Controlled Substance Registration for Stuart Feldman for Schedules II-V.

Second: Anna Carr

Action: Passed unanimously (Tomasso excused).

4.4 Application for Out-of-State Pharmacy License for a Pharmacy Intending to Engage in Compounding (NRS 639.2328) – Non-Appearance

4UU. Southend Pharmacy – Houston, TX

Agenda Item #4UU was on the Consent Agenda, but they needed to appear based on disclosures provided to the Board.

Kush Patel (CEO), Ronald Richardson (Managing Pharmacist), and Ngoc Estello (Regulatory Affairs) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve Out-of-State Pharmacy License for Southend Pharmacy.

Second: Jade Jacobo

Action: Passed unanimously (Tomasso excused).

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

Laura Tucker, Senior General Counsel for the Nevada Board of Pharmacy, presented.

19. Executive Secretary Report:

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

DRAFT

David Wuest, Executive Secretary for the Nevada Board of Pharmacy, presented.

21. Public Comment at 12:09PM

There was no public comment.

20. Date and Location of Next Scheduled Board Meeting:

October 14-15, 2026 – Las Vegas, NV

22. Adjournment

DRAFT

4

4A

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Care Prosthetics & Orthotics, Inc., d/b/a ForMotion Clinic

MDEG Physical Address: 1015 Swanson Street

City: Houston State: TX Zip: 77030

Mailing Address (if different from physical address): 102 Woodmont Blvd, STE 400

City: Nashville State: TN Zip: 37205

Telephone: +17135242813 Website: https://www.formotion.com/en-us/locations/formotion-clinic-houston-swansor

Email: lori.marler@formotion.com, casey.parham@formotion.com, atate@ossur.com

Name of MDEG Administrator (NAC 639.694): Casey Parham

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

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

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

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
PTAN 0479300001
TX Medicaid 091729602

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

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Texas

Parent Company (if any): _____

Corporation/Organization Name: Care Prosthetics & Orthotics, Inc., d/b/a ForMotion Clinic

Mailing Address: 102 Woodmont Blvd, STE 400

City: Nashville State: TN Zip: 37205

Telephone: 615-864-8790 Email: lori.marler@formotion.com

Contact Person Name: Lori Marler

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Lori Marler

Print Name of Authorized Person Submitting Application

Lori Marler

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

8.26.2026

Date

Board Use Only	Date Received: 8/27/26	Amount: $500.00

Docusign Envelope ID: 02C16A9E-CADD-8FCC-807C-78E43AD01D50

ForMotion™
CLINIC

Ownership Attestation

Attn:

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

Care Prosthetics & Orthotics, Inc., doing business as ForMotion Clinic, is a duly organized corporation. The corporation is owned through one or more corporate entities. The corporation does not have any individual persons who are shareholders, stockholders, partners, members, or owners. No individual persons hold a direct or indirect ownership interest of ten percent (10%) or greater in the company.
I declare that the foregoing is true and correct to the best of my knowledge and belief.

Care Prosthetics & Orthotics, Inc. d/b/a ForMotion Clinic

By: Signed by: Brad Gardner 396EBC700EE64B5...

Name: Brad Gardner

Title: Vice President

Date: August 26, 2026 | 19:45 GMT

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 8/12/2026

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

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

PRODUCER
Marsh & McLennan Agency LLC
Marsh & McLennan Ins. Agency LLC
PO Box 85638
San Diego CA 92186

License#: 0H18131 CTCMANAINC

CONTACT NAME: Mary Jones
PHONE (A/C, No, Ext): 858-587-7516 FAX (A/C, No): 858-909-9616
E-MAIL ADDRESS: Mary.Jones@marshmma.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Federal Insurance Company	20281
INSURER B : Chubb European Group Limited	55555
INSURER C : Twin City Fire Insurance Company	29459
INSURER D : Trumbull Insurance Company	27120
INSURER E :	
INSURER F :	

INSURED
CARE Prosthetics & Orthotics, Inc.
dba ForMotion Clinic
200 Spectrum Center Drive #700
Irvine CA 92618

COVERAGES **CERTIFICATE NUMBER:** 2046834318 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			99486110	5/31/2026	5/31/2027	EACH OCCURRENCE	$3,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$3,000,000
							MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$3,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$3,000,000
	OTHER:							$
D	AUTOMOBILE LIABILITY			72UENBF8NVK	10/31/2025	10/31/2026	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
B	X UMBRELLA LIAB X OCCUR			DKLSCA03184	6/1/2026	6/1/2027	EACH OCCURRENCE	$7,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$7,000,000
	DED RETENTION $						**see attached	$
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			72WEBA8GZM	10/31/2025	10/31/2026	X PER STATUTE OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N (Mandatory In NH)	N/A					E.L. EACH ACCIDENT	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$1,000,000
							E.L. DISEASE - POLICY LIMIT	$1,000,000
A	Professional Liability	N	N	99486110	5/31/2026	5/31/2027	$1,000,000 Each	$3,000,000 Agg

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
**see attached for further information on the excess policy.
EVIDENCE OF COVERAGE

CERTIFICATE HOLDER

CARE Prosthetics & Orthotics, Inc.
dba ForMotion Clinic
1015 Swanson St
Houston TX 77030

CANCELLATION

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

AUTHORIZED REPRESENTATIVE
Maxwell Bailey

© 1988-2015 ACORD CORPORATION. All rights reserved.

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Marsh & McLennan Insurance Agency LLC	CTC Management, Inc.
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Named Insured Schedule

CTC Management, Inc.
Abilities Unlimited, LLC
dba: ForMotion Clinic
Abilites Unlimited of Denver, LLC
dba: ForMotion Clinic
Adaptive Technologies, LLC
dba:ForMotion Clinic
Alabama Artificial Limb & Orthopedic Service, Inc. (AALOS)
dba: ForMotion Clinic
Anderson Prosthetics and Orthotics, LLC
dba: ForMotion Clinic
Applied Orthotic Systems, INC
dba: ForMotion Clinic
Baker O & P Enterprises, Inc.
dba: ForMotion Clinic
BCP Group Holdings, Inc.
dba: ForMotion Clinic
Bulow Holdings, LLC dba BCP Group
dba: BCP Group
dba: ForMotion Clinic
Bulow Management Holdings, LLC
dba: ForMotion Clinic
Bulow BioTech Prosthetics, LLC
dba: ForMotion Clinic
CARE Proshetics & Orthotics, Inc.
dba: ForMotion Clinic
Medical Center Orthotics and Prosthetics, LLC
dba: ForMotion Clinic
Next Step Bionics and Prosthetics, Inc.
dba: ForMotion Clinic
Precision Orthotics & Prosthetics, LLC
dba: ForMotion Clinic
Premier Prosthetics & Orthotics LLC
dba: ForMotion Clinic
Rocky Mountain Artificial Limb & Brace, Inc
dba: ForMotion Clinic
SRT Prosthetics & Orthotics, LLC
dba: ForMotion Clinic
Virginia Prosthetics, Inc.
dba: ForMotion Clinic
Xtreme Prosthetics, Inc.
dba: ForMotion Clinic

© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: _____

LOC #: _____

ADDITIONAL REMARKS SCHEDULE

AGENCY Marsh & McLennan Agency LLC	NAMED INSURED
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability

As respects Umbrella Liability policy# DKLSCA03184, Marsh & McLennan Insurance Agency LLC is generating and distributing this certificate in an administrative capacity. Marsh A/S Denmark is the broker for the defined policy. Chubb's primary underwriting operation in the UK and Europe is Chubb European Group SE which is rated "AA (Very Strong)" by Standard & Poor's and "A++ (Superior)" by A.M. Best.

© 2008 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

CHUBB

Kalvebod Brygge 45, 2. 1560 København V, Denmark
Telefon: +45 33 13 55 33 · Fax: +45 33 13 23 49
www.chubb.com

Marsh McLennan Agency US

06 may 2026

Certificates issued by Marsh US – William Demant Invest A/S
We hereby confirm that Marsh McLennan Agency USA is authorized to issue US certificates with Master policy information for Umbrella, Professional Liability and Autoexcess coverage, as below.

Named Insured:
William Demant Invest A/S
Kongebakken 9
2765 Smørum, Denmark

Or any US subsidiaries hereof.
Additional insureds can be added to the certificates.

Underwriting Company/Insurer:
Chubb European Group Limited

Policynumber:
DKLSCA03184

Policy Period:
From 00.00 hours 1st June 2026 to 24.00 hours 31th May 2027 (Central European Time).

Retail
Coverage:
Comprehensive General Liability, including Products/Completed Operations Liability and Professional Indemnity

Limit of Liability:
Maximum of USD 7,000,000 Master Umbrella limit (in excess of local USD 3,000,000 Limit) any one occurrence and in the aggregate.

Wholesale
Coverage:
Comprehensive General Liability, including Products/Completed Operations Liability

Limit of Liability:
Maximum of USD 9.000,000 Master Umbrella limit (in excess of local USD 1,000,000) any one occurrence and in the aggregate.

Territory:
USA and Canada

Autoexcess
Limit of Liability:
Maximum of USD 9.000,000 Master Umbrella limit (in excess of local USD 1,000,000) any one occurrence and in the aggregate.

Excess Employers Liability
Limit of Liability:
Maximum of USD 9.000,000 Master Umbrella limit (in excess of local USD 1,000,000) any one occurrence and in the aggregate.

Any Certificate of Insurance, issued in accordance with this authority, amends, extends nor alters the coverage afforded by the policy or policies mentioned herein.

Best Regards
CHUBB EUROPEAN GROUP LIMITED

Katrine Ravn
Phone: + 45 60 63 72 40 / E-mail: katrine.ravn@chubb.com

Chubb European Group, Danmark, filial af Chubb European Group SE, fransk forsikringsselskab - er en dansk filial registreret i CVR med organisationsnummer 27385931 og besøgsadresse: Kalvebod Brygge 45, 2. sal -1560 København V. Chubb European Group SE er en virksomhed, der er omfattet af bestemmelserne i den franske forsikringslovgivning med registreringsnummer 450 327 374 RCS Nanterre og følgende kontor: La Tour Carpe Diem, 31 Place des Corolles, Esplanade Nord, 92400 Courbevoie, Frankrig. Chubb European Group SE har fuldt indbetalt aktiekapital på 896 176 662 € og ledes af Autorité de contrôle prudentiel et de résolution (ACPR) 4, Place de Budapest, CS 92459, 75436 PARIS CEDEX 09. Den danske filial er også under tilsyn af Finanstilsynet.

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

Robert S. Howden
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Articles of Incorporation for CARE Prosthetics & Orthotics, Inc. (file number 13821200), a Domestic For-Profit Corporation, was filed in this office on February 28, 1957.

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

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on August 20, 2026.

Robert S. Howden
Secretary of State

ForMotion™
CLINIC

List of Officers and Directors:

Care Prosthetics & Orthotics, Inc., d/b/a ForMotion Clinic

1015 Swanson Street Houston, TX 77030

Section A:

Sveinn Sölvason – Director - 1015 Swanson St., Houston, TX 77030. Term expiration: 12/31/2050

Brad Gardner – Treasurer - 1015 Swanson St., Houston, TX 77030. Term expiration: 12/31/2050

Danny Shapiro – President - 1015 Swanson St., Houston, TX 77030. Term expiration: 12/31/2050

Andrew Tai – Secretary - 1015 Swanson St., Houston, TX 77030. Term expiration: 12/31/2050

Rick Figueroa
Chair

Thomas F. Butler
Vice Chair

Gerald R. Callas, M.D., F.A.S.A.
Nora Castañeda
Sujeeth Draksharam
Lori High, R.N., N.P., Retired
Gary F. Wesson, D.D.S., M.S.

Accredited Orthotic/Prosthetic Facility

CARE PROSTHETICS & ORTHOTICS

1015 SWANSON ST HOUSTON

License Number: 101688

The entity named above is licensed by the Texas Department of Licensing and Regulation.

License Expires: February 11, 2027

Courtney Arbour
Executive Director

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Care Prosthetics & Orthotics, Inc., d/b/a ForMotion Clinic MDEG License # (if applicable): _____

Physical Address: 1015 Swanson Street

City: Houston State: TX Zip: 77030

Mailing Address (if different from physical address): 102 Woodmont Blvd, STE 400

City: Nashville State: TN Zip: 37205

Telephone: 713-524-2813 Website: https://www.formotion.com/en-us/locations/formotion-clinic-houston-swans

Licensing Company Email: No email listed; TDLR Contact Us Page: www.tdlr.texas.gov/help/

Section 2: Personal Information

First: Casey Middle: _____ Last: Parham

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

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

Mailing Address: 1015 Swanson St

City: Houston State: TX Zip: 77030

Telephone: [redacted] Email: casey.parham@formotion.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Baylor College of Medicine		08/2013-05/2015	
Address	City	State	Zip
1 Baylor Plz	Houston	TX	77030
Diploma/Degree obtained, if any			
Masters of Prosthetics and Orthotics			
School Name		From - To (MM/YY – MM/YY)	
University of West Florida		08/2011-05/2013	
Address	City	State	Zip
11000 University Pkwy	Pensacola	FL	32514
Diploma/Degree obtained, if any			
Bachelors of Healthcare Administration			
School Name		From - To (MM/YY – MM/YY)	
Irvine Valley College		08/2008-05/2011	
Address	City	State	Zip
5500 Irvine Center Dr	Irvine	CA	92618
Diploma/Degree obtained, if any			
N/A			
School Name		From - To (MM/YY – MM/YY)	
Arnold O Beckman		08/2004-05/2008	
Address	City	State	Zip
3588 Bryan Ave	Irvine	CA	92602
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/25- present	[redacted]	Dickinson	TX	[redacted]
07/20-07-25		League City	TX	
07/18-07/20		Houston	TX	
07/16-07/18		Houston	TX	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Formotion Clinic			12/22-present	
Business Address		**City**	**State**	**Zip**
1015 Swanson St		Houston	TX	77030
Phone	**Title**		**Number of Employed Hours**	
713-795-8909	Clinic Manager		8,800	
Description of Duties				
Fit off the shelf and custom bracing products and prosthetic limbs and oversee clinicians				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8-27-26
Date

I, Casey Parham, **certify that as the MDEG Administrator for**

Care Prosthetics & Orthotics, Inc. d/b/a Formation Clinic,

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

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

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

Casey Parham
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8-27-24
Date

Board Use Only	Date Received: 8/31/2024

4B

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Milkmoms, Inc

MDEG Physical Address: 13783 Ibis St NW Ste 200

City: Andover State: MN Zip: 55304

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 763-259-8824 Website: www.milkmoms.com

Email: denzel@milkmoms.com

Name of MDEG Administrator (NAC 639.694): Denzel Uram

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	■ Others: Personal use Breast Pumps (HCPC E0603)
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: N/A
	Telephone: N/A

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 10:00-4:00	■ Tue: 10:00-4:00	■ Wed: 10:00-4:00	■ Thurs: 10:00-4:00	■ Fri: 10:00-4:00
☐ Sat:	☐ Sun:	☐ Holidays:		

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

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare PTAN: 7864480001
MN Medicaid: 000025941
WI Medicaid: 100167434
IA Medicaid: 0910573

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

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

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: MN

Parent Company (if any): N/A

Corporation/Organization Name: Milkmoms, Inc

Mailing Address: 13783 Ibis St NW Ste 200

City: Andover State: MN Zip: 55304

Telephone: 763-314-2096 Email: denzel@milkmoms.com

Contact Person Name: Denzel Uram

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Denzel Uram

Print Name of Authorized Person Submitting Application

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

08/14/26

Date

Board Use Only	Date Received: _____	Amount: $500 CK# 0676

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 8/22/2025

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

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

PRODUCER: VGM Insurance Services, Inc. 1111 Van Miller Way Waterloo IA 50701	CONTACT NAME: Michelle Newman PHONE (A/C, No, Ext): (800) 507-5736 FAX (A/C, No): E-MAIL ADDRESS: Michelle.Newman@vgm.com
INSURED: Milk Moms Inc Milk Moms 13783 Ibis St NW Ste200 Andover MN 55304	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: BENCHMARK INSURANCE COMPANY — 41394 INSURER B: INSURER C: INSURER D: INSURER E: INSURER F:

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			D1025 G6782-5	10/7/2025	10/7/2026	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
	X Professional Liability						MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	ALL OWNED AUTOS / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS / NON-OWNED AUTOS						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N/A (Mandatory in NH)						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

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

Locations:
13783 Ibis St NW Ste 200, Andover MN 55304
1714 Bunker Lake Blvd NW Ste 100, Andover MN 55304
1714 Bunker Lake Blvd NW Ste 102, Andover MN 55304

CERTIFICATE HOLDER

EVIDENCE OF INSURANCE

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2014 ACORD CORPORATION. All rights reserved.

Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	MILKMOMS, INC.
Date Filed:	01/24/2002
File Number:	11Z-84
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota

This certificate has been issued on: 08/14/2026

Steve Simon
Secretary of State
State of Minnesota

Milk Moms, Inc
Andover, MN 55304

Milk Moms, Inc.
Corporate Ownership and Officer List

Legal Business Name: Milk Moms, Inc.
State of Incorporation: Minnesota
Entity Type: S Corporation

Ownership

The following individuals hold ownership interests in Milk Moms, Inc.:

Owner Name	Ownership Percentage
Denzel Uram	20 %
Heather Gruba	80 %

Corporate Officers

The following individuals serve as officers of Milk Moms, Inc.:

Officer Name	Title
Heather Gruba	President
Denzel Uram	Vice President

I certify that the information provided above accurately reflects the current ownership and officer structure of Milk Moms, Inc.

Denzel Uram
Vice President
Milk Moms, Inc.

Milk Moms, Inc
Andover, MN 55304

Milkmoms, Inc.

Home State Licensure Verification Statement

To Whom It May Concern:

Milkmoms, Inc. is a durable medical equipment supplier physically located in the State of Minnesota.

Milkmoms, Inc. operates in compliance with all applicable licensing requirements in its home state of Minnesota. Minnesota does not require a durable medical equipment supplier whose operations are limited to the furnishing of medical devices and supplies, including personal-use electric breast pumps (HCPCS E0603), to obtain a separate state durable medical equipment supplier license.

Milkmoms, Inc. is not licensed as a pharmacy, drug wholesaler, manufacturer, or other entity regulated by the Minnesota Board of Pharmacy because the company does not manufacture, distribute, or dispense prescription drugs. The company furnishes FDA-cleared medical devices and supplies directly to patients.

As supporting documentation, we have attached a copy of the applicable Frequently Asked Questions (FAQ) published on the State of Minnesota website, which provides information regarding Minnesota's licensing requirements for durable medical equipment suppliers.

Please accept this statement and the attached State of Minnesota documentation as verification of our home-state licensure status.

Should additional information or documentation regarding our home-state licensing status be required, please contact us.

Sincerely,

Denzel Uram
Vice President
Milkmoms, Inc.

Does the Board have license verification on the internet?

Yes!

ONLINE VERIFICATION (https://pha.hlb.state.mn.us/#/onlineEntitySearch)

Does the Minnesota Board of Pharmacy license or register medical device or medical supply manufacturers, wholesale distributors, supplies or retailers?

The Board does not license or register companies that exclusively manufacture, distribute, supply or sell medical devices or supplies. If a company that handles medical devices or supplies also manufactures or distributes drugs, it must be licensed as a drug manufacturer or drug wholesaler. Exception if the drug is coated on or embedded in the device (e.g. drug-coated stents) and the resultant product is approved by the FDA as a device, the company does not have to be licensed as a manufacturer or wholesale distributor.

Miscellaneous

I received a telephone call from an individual claiming to work for the Board of Pharmacy or the Drug Enforcement Administration, but I think it was a scam. What information and advice can the Board provide?

For information about this, please click **here (/boards/assets/Scams%20FAQ%20February%202021_tcm21-469384.pdf)**.

Can I purchase a mailing list of licensees?

Yes. Contact Minnesota's Bookstore by phone at 651-201-3206 or fax at 651-215-5733. Please visit their website for more details: **Minnesota's Bookstore (https://mn.gov/admin/bookstore/)**

What do I need to do for my pharmacy to begin collecting discarded pharmaceuticals?

The answer can be found here. (https://www.pca.state.mn.us/sites/default/files/w-hhw2-07.pdf)

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Milkmoms, Inc

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

Physical Address 13783 Ibis St NW Ste 200

City Andover State MN Zip 55304

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 763-259-8824 Website www.milkmoms.com

Licensing Company Email denzel@milkmoms.com

Section 2: Personal Information

First Heather Middle _____ Last Gruba

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

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

Mailing Address [redacted]

City Gilbert State AZ Zip [redacted]

Telephone [redacted] Email heather@milkmoms.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
North Hennepin Community College		08/89-06/95	
Address	**City**	**State**	**Zip**
7411 85th Ave N	Brooklyn Park	MN	55445
Diploma/Degree obtained, if any			
Associate in Arts			

School Name		From - To (MM/YY – MM/YY)	
Columbia Heights High School		09/81-06/85	
Address	**City**	**State**	**Zip**
1400 49th Ave NE	Columbia Heights	MN	55421
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/16-10/25	[redacted]	Andover	MN	[redacted]
10/25-current		Gilbert	AZ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name: Milkmoms, Inc				From - To (MM/YY – MM/YY): 03/02-current
Business Address: 13783 Ibis St NW Ste 200		City: Andover	State: MN	Zip: 55304
Phone: 763-340-2833	Title: Owner			
Description of Duties: Day to day operations, sales				

Business Name: Bunker Lake Plaza LLC				From - To (MM/YY – MM/YY): 01/22-current
Business Address: 13783 Ibis St NW Ste 200		City: Andover	State: MN	Zip: 55304
Phone: 763-314-2096	Title: Owner			
Description of Duties: Day to day operations, property management				

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8/18/26
Date

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

Heather Gruba

Print Name (First, Last)

Heather Gruba

Original Signature (electronic, copies or stamps not accepted)

8/18/26

Date

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

State of Minnesota, ss. County of Anoka

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

Heather Gruba

Original Signature

8/18/26

Date

Subscribed and Sworn to before me this 18 day of August.

Notary Public Signature

Kayleah E. Heffron
Notary Public
Minnesota
My Commission Expires Jan. 31, 2031

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Milkmoms, Inc

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

Physical Address 13783 Ibis St NW Ste 200

City Andover State MN Zip 55304

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 763-259-8824 Website www.milkmoms.com

Licensing Company Email denzel@milkmoms.com

Section 2: Personal Information

First Denzel Middle _____ Last Uram

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

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

Mailing Address [redacted]

City Mound State MN Zip [redacted]

Telephone [redacted] Email denzel@milkmoms.com

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

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

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

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

School Name	From - To (MM/YY – MM/YY)
Andover High School	08/10-06/14

Address	City	State	Zip
2115 Andover Blvd NW	Andover	MN	55304

Diploma/Degree obtained, if any: High school diploma

School Name	From - To (MM/YY – MM/YY)
University of St. Thomas	

Address	City	State	Zip
2115 Summit Ave	St. Paul	MN	55105

Diploma/Degree obtained, if any: Bachelor of Arts

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY)

Address	City	State	Zip

Diploma/Degree obtained, if any:

School Name	From - To (MM/YY – MM/YY

Address	City	State	Zip

Diploma/Degree obtained, if any:

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/16-05/21	[redacted]	Andover	MN	[redacted]
05/21-09/25		Maple Grove	MN	
09/25-current		Mound	MN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name	From - To (MM/YY – MM/YY)
Milkmoms, Inc	02/24-current

Business Address	City	State	Zip
13783 Ibis St NW Ste 200	Andover	MN	55304

Phone	Title
763-314-2096	Vice President

Description of Duties
Day to day operations, sales, billing, compliance, contracting, credentialing

Business Name	From - To (MM/YY – MM/YY)
Bunker Lake Plaza LLC	01/22-current

Business Address	City	State	Zip
13783 Ibis St NW Ste 200	Andover	MN	55304

Phone	Title
763-314-2096	Owner

Description of Duties
Day to day operations, property management

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

08/14/26
Date

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

Denzel Uram

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/17/2026

Date

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

State of Minnesota, ss. County of Anoka

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

Original Signature

08/17/2026

Date

Subscribed and Sworn to before me this 17 day of August.

Notary Public Signature

Kayleah E. Heffron
Notary Public
Minnesota
My Commission Expires Jan. 31, 2031

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Milkmoms, Inc MDEG License # (if applicable) _____

Physical Address 13783 Ibis St NW Ste 200

City Andover State MN Zip 55304

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 763-259-8824 Website www.milkmoms.com

Licensing Company Email denzel@milkmoms.com

Section 2: Personal Information

First Denzel Middle _____ Last Uram

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

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

Mailing Address [redacted]

City Mound State MN Zip [redacted]

Telephone [redacted] Email denzel@milkmoms.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Andover High School		08/10-06/14	
Address	City	State	Zip
2115 Andover Blvd NW	Andover	MN	55304
Diploma/Degree obtained, if any			
High school diploma			
School Name		From - To (MM/YY – MM/YY)	
University of St. Thomas		08/14-06/18	
Address	City	State	Zip
2115 Summit Ave	St. Paul	MN	55105
Diploma/Degree obtained, if any			
Bachelor of Arts			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/16-05/21	[redacted]	Andover	MN	[redacted]
From - To (MM/YY – MM/YY)		City	State	
05/21-09/25		Maple Grove	MN	
From - To (MM/YY – MM/YY)		City	State	
09/25-current		Mound	MN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Milkmoms, Inc			02/24-current	
Business Address		**City**	**State**	**Zip**
13783 Ibis St NW Ste 200		Andover	MN	55304
Phone	**Title**		**Number of Employed Hours**	
763-314-2096	Vice President		5,000.00	
Description of Duties				
Day to day operations, sales, billing, compliance, contracting, credentialing				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

08/14/26
Date

I, Denzel Uram, **certify that as the MDEG Administrator for**

Milkmoms, Inc,

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

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

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

Denzel Uram
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/14/2026
Date

Board Use Only	Date Received:

4C

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Mountain West Medical Supply L.L.C.

MDEG Physical Address: 301 South Main Street

City: Blanding State: UT Zip: 84511

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 435.678.2239 Website: www.mwm-supply.com

Email: acton.eric@mwm-supply.com

Name of MDEG Administrator (NAC 639.694): Eric Acton

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	■ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	■ Others: See attachment with list of products
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Eric Acton Telephone: 435.678.2239

Check the Days the Business will be Opened and provide the Hours of Operation				
☑ Mon: 8:00a-5:00p	☑ Tue: 8:00a-5:00p	☑ Wed: 8:00a-5:00p	☑ Thurs: 8:00a-5:00p	☑ Fri: 8:00a-5:00p
☐ Sat: Closed	☐ Sun: Closed	☐ Holidays: Closed		

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

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
N/A - Please see accreditation supplement

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

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

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Utah

Parent Company (if any): UEW Acquisition LLC

Corporation/Organization Name: Mountain West Medical Supply L.L.C.

Mailing Address: 301 South Main Street

City: Blanding State: UT Zip: 84511

Telephone: 435.678.2239 Email: acton.eric@mwm-supply.com

Contact Person Name: Eric Acton

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Scott Whitt

Print Name of Authorized Person Submitting Application

Scott Whitt

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

8/5/2026

Date

Board Use Only	Date Received: 8/11/26	Amount: $500 ch 1388

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 8/5/2026

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

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

PRODUCER The Plexus Groupe 21805 W. Field Pkwy, Suite 300 Deer Park IL 60010	CONTACT NAME: Certificates PHONE (A/C, No, Ext): FAX (A/C, No): E-MAIL ADDRESS: certificates@plexusgroupe.com
INSURED UEWINTE-01 United Energy Workers Healthcare, LLC 614 E Main St Riverton WY 82501-4460	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Axis Surplus Insurance Company — 26620 INSURER B : Technology Insurance Company — 42376 INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** 550212691 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY [ ] PRO-JECT [ ] LOC OTHER:			P-001-001814327-01	11/6/2025	11/6/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 100,000 $ 5,000 $ 1,000,000 $ 3,000,000 $ Included
A	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY [ ] SCHEDULED AUTOS X HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			P-001-001814327-01	11/6/2025	11/6/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
A	X UMBRELLA LIAB [X] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED RETENTION $			P-001-001819764-01	11/6/2025	11/6/2026	EACH OCCURRENCE AGGREGATE	$ 5,000,000 $ 5,000,000
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N/A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			TWC4711053	11/6/2025	11/6/2026	X PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ 1,000,000 $ 1,000,000 $ 1,000,000
A	Errors & Omissions Prof Liab			P-001-001814327-01	11/6/2025	11/6/2026	Aggregate Limit Each Claim Limit	3,000,000 1,000,000

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

RE: HME Operations at 301 S Main St, Blanding, UT 84511

Certificate is issued as evidence of coverage.

CERTIFICATE HOLDER

Mountain West Medical Supply LLC
108 Oak Ridge Turnpike,
Oak Ridge, TN 37830
United States

CANCELLATION

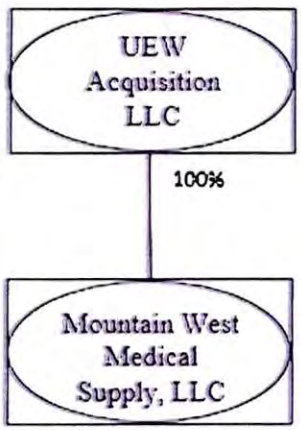
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

© 1988-2015 ACORD CORPORATION. All rights reserved.

Attachment 1

Organizational Chart



Attachment 4

Mountain West Medical Supply L.L.C. — Accreditation Supplement

The Nevada State Board of Pharmacy Medical Products Provider – Medical Devices, Equipment and Gases (MDEG) Application requests proof of accreditation, if applicable. Mountain West Medical Supply L.L.C. ("MWM") provides this supplement in response to that requirement.

MWM is not accredited or exempted by a national accrediting organization approved by the Centers for Medicare & Medicaid Services ("CMS"), such as The Joint Commission, Accreditation Commission for Health Care, or any similar CMS-approved accrediting body. Accordingly, no certificate of accreditation is included with this application.

MWM does not participate in or bill Medicare or Medicaid, and CMS-approved accreditation is not required for MWM's operations. MWM remains in compliance with all other applicable federal and state regulatory requirements for suppliers of durable medical equipment.

Attachment 5

Mountain West Medical Supply L.L.C. ("MWM") - List of Officers and Directors

Name	Title	Address
UEW Acquisition LLC	Owner – 100% direct owner of MWM	614 E Main Street, Ste C, Riverton, WY 82501
Scott Whitt	Chief Financial Officer	[redacted] Alpine, UT [redacted]
William ("Will") Burton	Chief Executive Officer	[redacted] West Haven, UT [redacted]

Note: UEW Acquisition LLC is the 100% owner of Mountain West Medical Supply L.L.C., with no natural human owners. William Burton and Scott Whitt are the only two individuals serving as officers of Mountain West Medical Supply L.L.C.

Attachment 6

Mountain West Medical Supply L.L.C.

List of Products

The following is a list of product categories distributed by Mountain West Medical Supply L.L.C., submitted in connection with the Nevada Medical Products Provider – Medical Devices, Equipment and Gases (MDEG) License Application:

No.	Product Category
1	Hospital Beds
2	Oxygen Concentrators
3	Nebulizers
4	CPAP Machines and Supplies
5	Various Types of Durable Medical Equipment (DME)

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LIMITED LICENSE

Mountain West Medical Supply, LLC

EFFECTIVE **06/22/2026**

EXPIRATION **12/22/2026**

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

14292625-1714 Pharmacy - Class E Business

Medical Gas Provider
Durable Medical Equipment Providers

DBA:

IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

MOUNTAIN WEST MEDICAL SUPPLY, LLC
301 S MAIN STREET
BLANDING UT 84511

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE

DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING

ACTIVE LIMITED LICENSE

EFFECTIVE DATE: **06/22/2026**

EXPIRATION DATE: **12/22/2026**

ISSUED TO: **Mountain West Medical Supply, LLC**
301 S Main Street
Blanding UT 84511

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

14292625-1714 **Pharmacy - Class E Business**

Medical Gas Provider
Durable Medical Equipment Providers

DBA:

Form #1

UTAH DEPARTMENT OF COMMERCE
Division of Corporations and Commercial Code

SPENCER J. COX
Governor

DEIDRE M. HENDERSON
Lieutenant Governor

MARGARET W. BUSSE
Executive Director

G. SCOTT WHITTAKER
Division Director

May 28, 2026

CERTIFICATE OF EXISTENCE

Registration Number:	7971497-0160
Business Name:	MOUNTAIN WEST MEDICAL SUPPLY L.L.C.
Principal Office Address:	301 S MAIN STREET, BLANDING, UT 84511
Registered Date:	06/01/2011
Entity Type:	DOMESTIC LIMITED LIABILITY COMPANY
Current Status:	ACTIVE - CURRENT

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

Scott Whittaker

G. Scott Whittaker
Director
Division of Corporations and Commercial Code

Certificate Number: 202605280914657
Enter the certificate number at https://businessregistration.utah.gov/ to verify this certification.

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Mountain West Medical Supply L.L.C.

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

Physical Address: 301 South Main Street

City: Blanding State: UT Zip: 84511

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 435.678.2239 Website: www.mwm-supply.com

Licensing Company Email: acton.eric@mwm-supply.com

Section 2: Personal Information

First: William Middle: Dickson Last: Burton

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

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

Mailing Address: [redacted]

City: West Haven State: UT Zip: [redacted]

Telephone: [redacted] Email: William.burton@uewhealth.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
University of Pennsylvania, The Wharton School		07/18 - 05/20	
Address	**City**	**State**	**Zip**
3733 Spruce St.	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
MBA - Healthcare and Finance			

School Name		From - To (MM/YY – MM/YY)	
Brigham Young University		01/11 - 08/14	
Address	**City**	**State**	**Zip**
155 East 1230 North	Provo	UT	84602
Diploma/Degree obtained, if any			
Bachelor's Degree - Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Brigham Young University		08/08 - 01/09	
Address	**City**	**State**	**Zip**
155 East 1230 North	Provo	UT	84602
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Woods Cross High School		08/05 - 05/08	
Address	**City**	**State**	**Zip**
600 W 2200 S.	Woods Cross	UT	84087
Diploma/Degree obtained, if any			
Diploma			

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/23 - Current	[redacted]	Taylor	UT	[redacted]
09/22 - 05/23		North Ogden	UT	
07/20 - 09/22		West Chester	OH	
07/18 - 03/20		Philadelphia	PA	
01/17 - 07/18		Colorado Springs	CO	
07/15 - 01/17		Denver	CO	

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

Business Name			From - To (MM/YY – MM/YY)
UEW Acquisition LLC			10/22 - Current
Business Address	**City**	**State**	**Zip**
614 E Main Street, Ste C	Riverton	WY	82501
Phone	**Title**		
435.678.2194	President		

Description of Duties

Contractor (1099) - Chief of Staff, then assumed President role in 04/2023 - over Operations, Sales, Marketing, HR, Talent Acquisition

Business Name			From - To (MM/YY – MM/YY)
BrightView Healthcare			05/20 - 09/22
Business Address	**City**	**State**	**Zip**
446 Morgan St.	Cincinnati	OH	45206
Phone	**Title**		
(833) 510-3278	Chief of Staff/Chief Strategy Officer		

Description of Duties

Oversaw M&A, integration, Ohio/Kentucky operations

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

Description of Duties

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8/5/26
Date

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

WILLIAM BURTON

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/5/26

Date

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

State of Utah, ss. County of Salt Lake

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

Original Signature

8/5/2026

Date

Subscribed and Sworn to before me this 26 day of August.

Notary Public Signature

HOLLY THOMPSON
NOTARY PUBLIC - STATE OF UTAH
My Comm. Exp. 09/18/2029
Commission # 745241

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Mountain West Medical Supply L.L.C.

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

Physical Address: 301 South Main Street

City: Blanding State: UT Zip: 84511

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 435.678.2239 Website: www.mwm-supply.com

Licensing Company Email: acton.eric@mwm-supply.com

Section 2: Personal Information

First: Scott Middle: Nicholas Last: Whitt

Alias(es, nicknames, name changes, etc.): None

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

Mailing Address: [redacted]

City: Alpine State: UT Zip: [redacted]

Telephone: [redacted] Email: scott.whitt@uewhealth.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Stanford University		08/92 - 06/96	
Address	**City**	**State**	**Zip**
450 Jane Stanford Way	Stanford	CA	94305
Diploma/Degree obtained, if any			
BS Chemical Engineering			

School Name		From - To (MM/YY – MM/YY)	
James Madison High School		09/86 - 06/90	
Address	**City**	**State**	**Zip**
2500 James Madison Drive	Vienna	VA	22181
Diploma/Degree obtained, if any			
Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/10 - Current	[redacted]	Alpine	UT	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
UEW Acquisition LLC / United Energy Workers Healthcare			03/23 - Current	
Business Address		**City**	**State**	**Zip**
614 E Main Street, Ste C		Riverton	WY	82501
Phone	**Title**			
435.678.2194	Chief Financial Officer			
Description of Duties				
Financial strategy & growth, cash & capital management, financial reporting & compliance, risk management, M&A & deal structuring, operational efficiency				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Scott White

Original Signature (electronic, copies or stamps not accepted)

8/5/2026

Date

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

Scott Whitt

Print Name (First, Last)

Scott White

Original Signature (electronic, copies or stamps not accepted)

8/5/2026

Date

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

State of Utah, ss. County of Salt Lake

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

Original Signature

8/5/2026

Date

Subscribed and Sworn to before me this 5 day of August.

Notary Public Signature

HOLLY THOMPSON
NOTARY PUBLIC - STATE OF UTAH
My Comm. Exp. 09/18/2029
Commission # 745241

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Mountain West Medical Supply L.L.C. MDEG License # (if applicable): N/A

Physical Address: 301 South Main Street

City: Blanding State: UT Zip: 84511

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 435.678.2239 Website: www.mwm-supply.com

Licensing Company Email: acton.eric@mwm-supply.com

Section 2: Personal Information

First: Kim Middle: Eric Last: Acton

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

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

Mailing Address: [redacted]

City: Blanding State: UT Zip: [redacted]

Telephone: [redacted] Email: acton.eric@mwm-supply.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Utah Valley University - Orem Utah		08/03-12/07	
Address	**City**	**State**	**Zip**
800 W. University Pkwy	Orem	UT	84058
Diploma/Degree obtained, if any			
Bachelor of Science in Accounting			
School Name		**From - To (MM/YY – MM/YY)**	
San Jaun High		08/94-05/98	
Address	**City**	**State**	**Zip**
311 N. 100 E.	Blanding	UT	84511
Diploma/Degree obtained, if any			
High School Diploma			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/15-07/26	[redacted]	Blanding	UT	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Mountain West Medical Supply L.L.C.			07/2020 - Current	
Business Address	**City**		**State**	**Zip**
301 South Main Street	Blanding		UT	84511
Phone	**Title**		**Number of Employed Hours**	
435.678.2239	Director of HME Operations		10,000+ hours	
Description of Duties				
Oversee entire operation of MWMS LLC, manage a team of 20+ individuals, directing equipment and supply delivery to patients, ordering and managing supplies, insurance authorization, billing and collection, marketing and growth strategy. I have worked from July 1st 2020 to current at roughly 40 hrs/wk				

Business Name			From - To (MM/YY – MM/YY)	
Sysco Intermountain Wyoming			03/10 - 07/20	
Business Address	**City**		**State**	**Zip**
9494 S. Prosperity Road	West Jordan		UT	84081
Phone	**Title**		**Number of Employed Hours**	
801.563.6300	Utah Sales Associate		10,000+ hours	
Description of Duties				
Develop and maintain relationship with customers for repeat sales; develop and implement business analytics for each customer business; implement business strategy to ensure customer success and profit; drive revenue growth				

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

8-3-26

Date

I, Eric Acton, **certify that as the MDEG Administrator for**

Mountain West Medical Supply L.L.C.,

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

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

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

Eric Acton
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8-3-26
Date

Board Use Only	Date Received: 8/11/26

Attachment 12

Copy of Proof of Insurance

Removed by McGuireWoods while shipping to MWM to cut down on package weight. McGuireWoods to include before shipping to NV

McGuireWoods

McGuireWoods LLP
77 West Wacker Drive
Suite 4100
Chicago, IL 60601-1818
Phone: 312.849.8100
Fax: 312.849.3690
www.mcguirewoods.com

Kristen H. Chang
Direct: 312.750.3538
kchang@mcguirewoods.com
Fax: 312.698.3690

August 3, 2026

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, Nevada 89521

Re: New Application for Medical Products Provider – Medical Devices, Equipment and Gases (MDEG) License

To Whom It May Concern:

We are writing to the Nevada State Board of Pharmacy (the "***Board***") to submit a new Medical Products Provider – Medical Devices, Equipment and Gases (MDEG) Application (the "***Application***") on behalf of Mountain West Medical Supply L.L.C. ("***MWM***"), located at 301 S. Main Street, Blanding, UT 84511 (the "***Location***"). MWM does not currently hold, and has not previously held, a Nevada MDEG license. We submit the enclosed Application, with the "New MDEG" box checked, to obtain Nevada licensure for MWM.

MWM is seeking to expand its operations into Nevada. MWM continues to operate from the Location in Utah, and we are enclosing a copy of MWM's Utah home-state license and evidence of MWM's good standing in its home state.

The information contained in, or provided with, this letter is confidential. Should you have any questions or need further information, please do not hesitate to contact Kristen Chang, at kchang@mcguirewoods.com or (312) 750-3538. Thank you for your review and consideration.

Sincerely,

K. Chang

Enclosures:

1. Organizational Chart
2. Application Fee Check ($500.00, non-refundable)
3. Medical Products Provider – Medical Devices, Equipment and Gases (MDEG) Application
4. Accreditation Supplement
5. List of All Officers and Directors
6. List of Products
7. Copy of Utah Home-State License
8. Certificate of Good Standing (dated within the last 6 months)
9. Personal History Application(s) – Will Burton
10. Personal History Application(s) – Scott Whitt
11. MDEG Administrator Application
12. Certificate of Liability Insurance (at least $1,000,000)

4D

NEVADA STATE BOARD OF PHARMACY

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

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

Non-Refundable $500 fee

Rev (05/12/2022)

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

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

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

Section 1: General Information

Facility Name: Serenity Medical Supply

MDEG Physical Address: 88 Industrial Ct Ste A

City: Freehold State: NJ Zip: 07728

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 8488636468 Website: www.serenitymedicalsupply.com

Email: info@serenitymedicalsupply.com

Name of MDEG Administrator (NAC 639.694): Zev Felder

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

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 10AM-5PM	■ Tue: 10AM-5PM	■ Wed: 10AM-5PM	■ Thurs: 10AM-5PM	■ Fri: 10AM-12PM
☐ Sat:	☐ Sun:	☐ Holidays:		

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

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))			
Medicare 8151780001	AR Medicaid 313561741	PA Medicaid 104157369-0001	RI Medicaid 1851012603
NJ Medicaid 0905585			
GA Medicaid 003287655A			
NY Medicaid 07529606			

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 639.6939)

Name: NA Credentials: _____ %: _____

Name: NA Credentials: _____ %: _____

Name: NA Credentials: _____ %: _____

Name: NA Credentials: _____ %: _____

Name: NA Credentials: _____ %: _____

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

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: Serenity Medical Supply LLC

Mailing Address: 88 Industrial Ct Ste A

City: Freehold State: NJ Zip: 07728

Telephone: 8488636468 Email: info@serenitymedicalsupply.com

Contact Person Name: Zev Felder

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

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

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

Zev Felder

Print Name of Authorized Person Submitting Application

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

07/30/2026

Date

Board Use Only	Date Received: 8/6/26	Amount: $500 ch 147

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 8/12/2026

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

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

PRODUCER
PRIME INSURANCE AGENCY
960 E County Line Road
Lakewood NJ 08701

License#: BR-1000439

CONTACT NAME:
PHONE (A/C, No, Ext): 732-886-5751 | FAX (A/C, No): 732-886-9422
E-MAIL ADDRESS: PRIME@primeins.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Philadelphia Indemnity Insuran	18058
INSURER B :	
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Serenity Medical Supply LLC
88 Industrial Ct
Ste A
Freehold NJ 07728-8908
SEREMED-01

COVERAGES **CERTIFICATE NUMBER:** 1291207316 **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			PHPK2747518-000	8/7/2026	8/7/2027	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE [X] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY [ ] PRO-JECT [ ] LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	X UMBRELLA LIAB [X] OCCUR			PHUB931203-000	8/7/2026	8/7/2027	EACH OCCURRENCE	$ 1,000,000
	EXCESS LIAB [ ] CLAIMS-MADE						AGGREGATE	$ 1,000,000
	DED [X] RETENTION $ 10,000							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N/A (Mandatory in NH)						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Professional Liability			PHPK2747518-000	8/7/2026	8/7/2027	Per occurrence Aggregate	1,000,000 3,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Certificate is subject to terms, limitations and exclusions of the actual policy at the time of issuance.

CERTIFICATE HOLDER

Proof of Coverage

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2015 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

serenity
MEDICAL SUPPLY

PHONE 848-863-6468 | FAX 732-491-8797

88 Industrial Court, Suite A | Freehold, NJ 07728

To whom it may concern,

8/11/2026

This letter serves to confirm that Serenity Medical Supply does not have any officers or directors.

Zev Felder

Serenity Medical Supply

serenity
MEDICAL SUPPLY
PHONE 848-863-6468 | FAX 732-491-8797 88 Industrial Court, Suite A | Freehold, NJ 07728

Please see below list of all general and limited partner names and their percent ownership in Serenity Medical Supply.

Zev Felder – 50%

Alan Muller – 50%

Zev Felder DOB [redacted] ackson NJ [redacted]
Alan Muller DOB [redacted] Howell NJ

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

SERENITY MEDICAL SUPPLY LLC
0450854449

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic Limited Liability Company was registered by this office on August 25, 2022.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

ZEV FELDER
88 INDUSTRIAL COURT
SUITE A
FREEHOLD, NJ 07728

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 3rd day of August, 2026

Aaron Binder
State Treasurer

Certificate Number : 3011022759

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 369
TRENTON, N.J. 08625-0369
www.nj.gov/health

MIKIE SHERRILL
Governor

DR. DALE G. CALDWELL
Lt. Governor

DR. RAYNARD E. WASHINGTON
Commissioner

July 23, 2026

Re: Oversight of durable medical equipment providers

The New Jersey Department of Health, Wholesale Drug Project, does not register and/or license direct-to-patient durable medical equipment providers.

Sincerely,

Eric B. Lieberman, Esq.
Project Coordinator, Wholesale Drug Project
Public Health and Food Protection Program

Environmental Health

Public Health and Food Protection Program

Eric Lieberman
Project Coordinator

Jennifer Steffee
Project Specialist

dmd@doh.nj.gov

(609)913-5287

Wholesale Food

Retail Food

Dairy

Bottled Water

Shellfish

Drug and Medical Device Registration

Export Documents

Youth Camps

Public Recreational Bathing

Tanning Facilities

Nitrous Oxide

Body Art

General Sanitation Resources

Drug and Medical Device Registration

New Jersey law requires any business that distributes prescription or non-prescription drugs or medical devices to register with the Department of Health. This registration ensures compliance with NJAC 8:21-3A and helps protect the health and safety of consumers by maintaining high standards for storage, handling, distribution, and records.

Frequently Asked Questions

Registration Verification

Verify a Registration

License Verification Forms for Other State Agency Applications are Not Accepted

Verify Wholesale Drug Distributor Licenses in Other States

Verify FDA Registration and Inspection Information

Rules and Definitions

See the Wholesale Drug Rules (N.J.A.C. 8:21-3A and N.J.S.A. 24:6B) for a full list of definitions, qualifications, and requirements.

NJAC 8:21-3A.3

"**Drug**" shall have the meaning set forth at N.J.S.A. 24:1-1 and as used throughout this subchapter shall include both non-prescription and prescription drugs.

"**Non-prescription or Non-legend or O.T.C. drugs**" mean drugs directly available to the consumer over the counter, without a physician's prescription.

"**Prescription drug**" means any human drug required by Federal law or regulation to be dispensed only by a prescription, including dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug and Cosmetic Act.

"**Wholesale Distribution**" means the distribution of drugs or devices to persons other than a consumer or patient.

"**Wholesale Distributor**" means anyone engaged in wholesale distribution including, but not limited to, manufacturers; repackagers; own-label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug

warehouses; and independent wholesale drug traders, but does not include a retail pharmacy whose sales of prescription drugs to other than the ultimate user, including physicians for office use, nursing homes, institutions, etc. does not exceed five percent of the total gross annual sales of prescription drugs of the pharmacy.

"**Manufacturer**" means anyone who is engaged in the manufacturing of drugs or devices, or engaged in the manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug.

"**Designated Representative**" means an individual who is designated by a wholesale distributor to serve as the primary contact person for the wholesale distributor with the Department, and who is responsible for managing the company's operations at that licensed location.

NJSA 24:6B

24:1-1. Definitions as used in this Title

"**Drugs**" means (1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

"**Device**" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

24:6B-12. Definitions

"**Distribute**" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a prescription drug, whether by passage of title, physical movement, or both. The term does not mean to: dispense or administer; deliver or offer to deliver in the usual course of business as a common carrier or logistics provider, or provide a sample to a patient by a licensed practitioner, a health care professional acting at the direction and under the supervision of a practitioner, or the pharmacist of a health care facility licensed pursuant to P.L.1971, c.136 (C.26:2H-1 et seq.) acting at the direction of a practitioner.

"**Drugs**" means "drugs" and "devices" as defined in R.S.24:1-1

"**Drugs manufacturing business**" means the business of creating, making, or producing drugs by compounding, growing, or other process. This definition shall apply to persons engaged in the drug manufacturing business who do not maintain a manufacturing location in this State but do operate distribution depots or warehouses of such business in this State. This definition shall not apply to licensed pharmacies or to licensed professional individuals such as, but not limited to, pharmacists, physicians, dentists, or veterinarians when engaged in the lawful pursuit of their professions.

24:6B-14 Definitions relative to pharmaceutical wholesale distributors

"**Drug**" means: a. an article or substance recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to any of them; b. an article or substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; c. an article or substance, other than food, intended to affect

the structure of any function of the body of man or animals; and d. an article or substance intended for use as a component of any article or substance specified in clause a., b., or c.; but does not include devices or their components, parts, or accessories. **Drug includes a prefilled syringe or needle.**

Related Registrations and Inquiries

Controlled Dangerous Substance Registration: Manufacturers and wholesalers must register with the **New Jersey Drug Control Unit** if they will handle controlled dangerous substances. The State of New Jersey has established a Drug Control Unit within **the Department of Law and Public Safety**, for the purpose of assisting in the enforcement of those provisions of the New Jersey Controlled Dangerous Substances (CDS) Act which relate to persons who, or firms that, manufacture, prescribe, distribute, dispense or conduct research or analysis utilizing controlled substances. To register to handle CDS, please contact the New Jersey Drug Control Unit.

Logistics Provider means an entity that receives drugs from the original manufacturer and delivers them at the direction of that manufacturer, and does not purchase, sell, trade, or take title to the drugs. Logistics Providers are not wholesale distributors and may not register. Logistics Providers that are located in New Jersey and are engaged in the storage or packing of food, vitamin supplements, or cosmetics must register as a wholesale food-cosmetic establishment.

Durable Medical Equipment Provider means an entity that delivers durable medical equipment directly to the consumer or patient. Durable Medical Equipment Providers which do not conduct wholesale distribution business may not register. Licensure for Durable Medical Equipment Providers is not available through this office. Consult your local Medicare/Medicaid office for further guidance.

Vitamin Supplement or Cosmetic Manufacturers or Distributors which operate a facility in New Jersey that stores or manufactures vitamin supplements or cosmetics must register as a wholesale food-cosmetic establishment.

The New Jersey Cannabis Regulatory Commission establishes and enforces the rules and regulations governing the licensing, cultivation, testing, selling, and purchasing of cannabis in the state.

Initial Applications

1. Download the initial application form

Submit only when applying for a new registration. All submissions of form F-2 will result in the creation of a new registration number. Do not submit form F-2 if a current registration exists for the registered applicant. Please allow 4 weeks for application review. Expedited service is not available. At the conclusion of review, if more information is needed, a letter will be mailed to the applicant. If the registrant facility is in New Jersey, an inspector will reach out directly to the Designated Representative to schedule an inspection.

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Serenity Medical Supply LLC

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

Physical Address: 88 Industrial Court STE A

City: Freehold State: NJ Zip: 07728

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 84886336468 Website: https://serenitymedicalsupply.com/

Licensing Company Email: info@serenitymedicalsupply.com

Section 2: Personal Information

First: Alan Middle: Last: Muller

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

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

Mailing Address: [redacted]

City: Howell State: NJ Zip: [redacted]

Telephone: [redacted] Email: alan@serenitymedicalsupply.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)
Beth Medrash Govoha			05/16-12/19
Address	**City**	**State**	**Zip**
617 6th St	617 6th St	NJ	08701
Diploma/Degree obtained, if any			
NA			

School Name			From - To (MM/YY – MM/YY)
Mesivta Tiferes Rav Zvi Aryeh Zemel			09/09-07/13
Address	**City**	**State**	**Zip**
15 Temple Pl	Passaic	NJ	07055
Diploma/Degree obtained, if any			
NA			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/25-Present	[redacted]	Howell	NJ	[redacted]
08/22-04/25		Lakewood	NJ	
12/19-08/22		Lakewood	NJ	
04/91-12/19		Brooklyn	NY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Serenity Medical Supply LLC			08/22-Present	
Business Address		**City**	**State**	**Zip**
88 Industrial Ct STE A		Freehold	NJ	07728
Phone	**Title**			
8488636468	CEO			
Description of Duties				
Overseeing the entire company				

Business Name			From - To (MM/YY – MM/YY)	
ZAM Advertising LLC			08/22-Present	
Business Address		**City**	**State**	**Zip**
21 Devon Drive		Howell	NJ	07731
Phone	**Title**			
3477600465	CEO			
Description of Duties				
Overseeing the entire company				

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

_____ _____

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

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

Alan Muller

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/30/2026

Date

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

State of New Jersey, ss. County of Monmouth

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

Original Signature

8/4/2026

Date

Subscribed and Sworn to before me this 4th day of August, 2026.

Notary Public Signature

JASON MARCINIAK
Notary Public, State of New Jersey
Comm. # 50234243
My Commission Expires 8/5/2030

JASON MARCINIAK NOTARY PUBLIC STATE OF NEW JERSEY

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Serenity Medical Supply

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

Physical Address: 88 Industrial Ct Ste A

City: Freehold State: NJ Zip: 07728

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: Website: www.serenitymedicalsupply.com

Licensing Company Email: www.serenitymedicalsupply.com

Section 2: Personal Information

First: Zev Middle: Last: Felder

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

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

Mailing Address: [redacted]

City: Jackson State: NJ Zip: [redacted]

Telephone: [redacted] Email: zev@serenitymedicalsupply.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)
Beth Medrash Govoha			09-14-09-20
Address	**City**	**State**	**Zip**
617 6th Street	Lakewood	NJ	08701
Diploma/Degree obtained, if any			
Bachelors Degree			
School Name			**From - To (MM/YY – MM/YY)**
Mesivta TiferesR' Tzvi Aryeh Zemel z"l			09/05-09/09
Address	**City**	**State**	**Zip**
15 Temple Place	Passaic	NJ	07055
Diploma/Degree obtained, if any			
High School Diploma			
School Name			**From - To (MM/YY – MM/YY)**
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name			**From - To (MM/YY – MM/YY)**
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name			**From - To (MM/YY – MM/YY**
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/25 - Current	[redacted]	Jackson	NJ	[redacted]
10/18-02/25		Lakewood	NJ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Serenity Medical Supply LLC			08/22-Current	
Business Address		**City**	**State**	**Zip**
88 Indsutrial Ct Ste A		Freehold	NJ	07728
Phone	**Title**			
8488636468	Owner			
Description of Duties				
As the business owner, I oversee compliance, order fulfillment, customer service issues, financials, Medicare/Medicaid enrollment, and staff management.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

_____ _____

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

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

Zev Felder

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/30/2026

Date

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

State of New Jersey, ss. County of Ocean

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

Original Signature

8/5/26

Date

Subscribed and Sworn to before me this 5th day of August.

Notary Public Signature

MACKINLEY BYRNE
Notary Public, State of New Jersey
Commission # 50234099
My Commission Expires Jun 2, 2030

(Seal)

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Serenity Medical Supply LLC — MDEG License # (if applicable): _____

Physical Address: 88 Industrial Ct Ste A

City: Freehold — State: NJ — Zip: 07728

Mailing Address (if different from physical address): _____

City: _____ — State: _____ — Zip: _____

Telephone: 8488636468 — Website: www.serenitymedicalsupply.com

Licensing Company Email: info@serenitymedicalsupply.com

Section 2: Personal Information

First: Zev — Middle: _____ — Last: Felder

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

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

Mailing Address: [redacted]

City: Freehold — State: NJ — Zip: [redacted]

Telephone: [redacted] — Email: zev@serenitymedicalsupply.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Beth Medrash Govoha		09-14-09-20	
Address	**City**	**State**	**Zip**
617 6th Street	Lakewood	NJ	08701
Diploma/Degree obtained, if any			
Bachelors Degree			

School Name		From - To (MM/YY – MM/YY)	
Mesivta Tiferes R' Tzvi Aryeh Zemel z"l			
Address	**City**	**State**	**Zip**
15 Temple Place	Passaic	NJ	07055
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/25 - Current	[redacted]	Jackson	NJ	[redacted]
From - To (MM/YY – MM/YY)		City	State	
10/18-02/25		Lakewood	NJ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Serenity Medical Supply LLC			08/22- Current	
Business Address		**City**	**State**	**Zip**
88 Industrial Ct Ste A		Freehold	NJ	07728
Phone	**Title**		**Number of Employed Hours**	
8488636468	Owner		~8000	

Description of Duties

I have been the co-owner of Serenity Medical Supply since 08/2022. As the business owner, I oversee compliance, order fulfillment, customer service issues, financials, Medicare/Medicaid enrollment, and staff management.

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

Description of Duties

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

Description of Duties

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

Description of Duties

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

Description of Duties

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

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

I, Zev Felder, **certify that as the MDEG Administrator for**

Serenity Medical Supply LLC,

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

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

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

Zev Felder

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/03/2026

Date

Board Use Only	Date Received: 8/6/26

Board of Certification/Accreditation

Owings Mills, Maryland

Accredited Facility

Practice limited to DMEPOS supplier categories:
DM02, DM03, DM05, DM06, DM08, DM11, DM12, DM13, DM16, DM17, DM18, DM20, DM21, DM22, DM23, DM24, DM25, DM26, M01, M04, M05, M10, OR03, OR04, PD04, PD06, PD08, PD09, PE03, PE04, S01

The Board of Certification/Accreditation attests that the Facility named below complies with all requirements for facility accreditation.

Serenity Medical Supply

88 Industrial Ct Ste A
Freehold, New Jersey 07728-8898

This accreditation is awarded for meeting the professional standards of BOC, together with all the honors, rights, privileges and responsibilities in pursuit of our mission to assure patients, physicians, professional organizations, the public at large, and government agencies and representatives of the competence and professionalism of BOC-Accredited Facilities.
In witness whereof, we have affixed the seal of the Board and subscribed our names in acknowledgment.

Matthew Gruskin, MBA, BOCO, BOCPD, CDME, Chief Operating Officer

Judi L. Knott, MA, MBA, President & CEO

S62995
Facility Number

October 31, 2028
Accredited Through

Accredited Since: October 20, 2022

BOC is a CMS deemed accrediting organization.

This accreditation is the property of BOC — the certificate holder agreas to abide by the BOC and CMS standards.

0154

10461 Mill Run Circle, Suite 1250 • Owings Mills, MD 21117
phone 877.776.2200 • *local* 410.581.6222 • *fax* 410.581.6228 • *online* www.bocusa.org

October 08, 2025

Serenity Medical Supply
88 Industrial Ct Ste A
Freehold, New Jersey 07728-8898

Dear Serenity Medical Supply.,

We are pleased to inform you that Serenity Medical Supply, meets the accreditation requirements of the Board of Certification/Accreditation (BOC). BOC standards meet the DMEPOS accreditation requirements under section 1834 (a)(20) of the Social Security Act (SSA) and the federal regulations at 42 CFR 424.58. BOC based its decisions on a review of your application and site survey conducted on **September 29, 2025.**

BOC has approved Serenity Medical Supply. whose NPI number is **1851012603** for an effective date of **October 31, 2025,** through **October 31, 2028** for the following DMEPOS product categories:

DM02, DM03, DM05, DM06, DM08, DM11, DM12, DM13, DM16, DM17, DM18, DM20, DM21, DM22, DM23 DM24, DM25, DM26, M01, M04, M05, M10, OR03, OR04, PD04, PD06, PD08, PD09, PE03, PE04, S01
(Please see the attached for an explanation of the codes.)

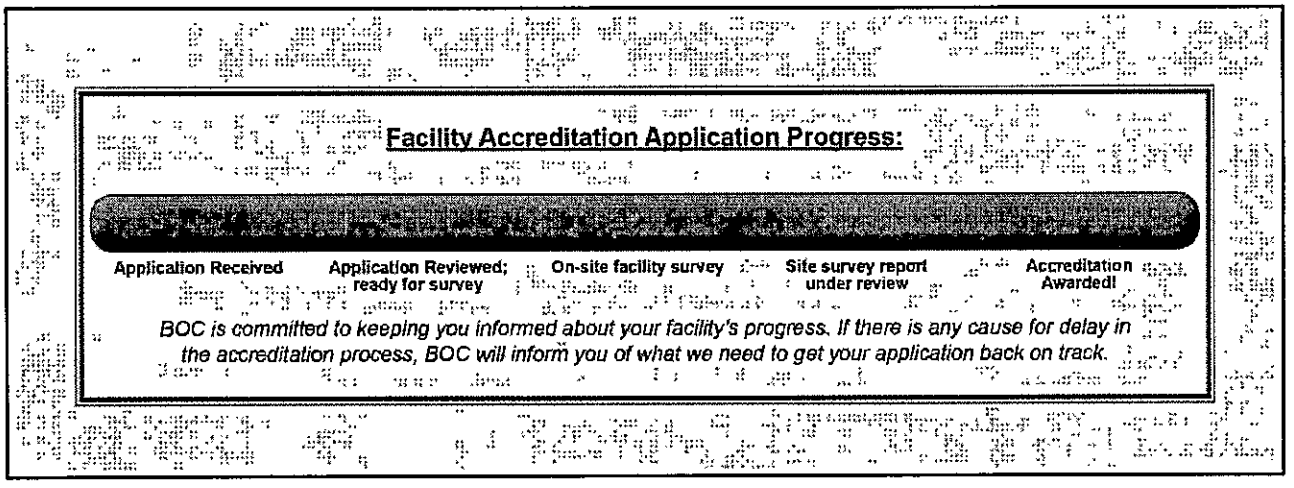
The enclosed certificate demonstrates to the public that Serenity Medical Supply., is a BOC-accredited facility. Your accreditation is valid through the date listed on your certificate.

Please provide feedback on your recent site survey, as well as any additional feedback on the accreditation process at www.bocusa.org/surveyor. The information you provide will be used for BOC to continue to improve.

Thank you for your continued commitment to patient care. We look forward to continuing our partnership with you. If you have any questions, please contact the BOC Facility Accreditation Team at 410.581.6222 or fa@bocusa.org.

Sincerely,
BOC Facility Accreditation Team

P.S. Have you heard about the Certified DME Specialist, an individual certification acknowledging the professionalism of your employees? Find out more at http://cdme.org.



4E

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Medline Industries, LP

Physical Address: 21111 E. 36th Dr.

City: Aurora State: CO Zip: 80011

Mailing Address (if different from physical address): Three Lakes Drive - 3D

City: Northfield State: IL Zip: 60093

Telephone: 303-371-8546 Website: www.medline.com

Name of Designated Representative (DR): Angelica Chavez

Licensing Company Email: ralicensing@medline.com DR Email: achavez@medline.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☒ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☒ Warehouse
☒ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Assisted living, nursing homes, surgical centers.		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Pfizer, Inc.
Address: 66 Hudson Blvd. E City: New York State: NY Zip: 10001

Name: ICU Medical Inc.
Address: 951 Calle Amanecer City: San Clemente State: CA Zip: 92673

Name: Baxter Healthcare Inc.
Address: One Baxter Parkway City: Deerfield State: IL Zip: 60015

Name: B Braun Medical Inc.
Address: 824 12th Avenue City: Bethlehem State: PA Zip: 18018

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): Medline Inc.
Corporation Name: See Attached Ownership Information
Mailing Address: Three Lakes Drive
City: Northfield State: IL Zip: 60093
Telephone: 847-949-5500 Email: ralicensing@medline.com
Contact Person Name: Daniel Stevens [redacted]

Date of SEC Registration: 12/17/2025 | SEC Registration Number: 0002046386 | Stock Exchange Symbol: MDLN

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	X	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		X
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
N/A • **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Medline Industries, LP

Facility Name

Daniel Stevens - Manager of Regulatory Affairs (POA)

Print Name of Authorized Person Submitting Application

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

08/11/26

Date

Board Use Only	Date Received: 8/17/26	Amount: $1000.00

POWER OF ATTORNEY

MEDLINE INDUSTRIES, LP, an Illinois limited partnership, having a principal place of business at 3 Lakes Dr, Northfield, Illinois, 60093 (the "Company"), herewith authorizes and entrusts a Power of Attorney to DANIEL A. STEVENS, United States citizen, Manager, Regulatory Affairs, with permanent residence at 4369 Vulcan Drive, Sacramento, California 95864 with full signatory rights on behalf of the Company as follows:

To be our true and lawful Agent with as full as legally necessary powers to submit, execute and prosecute applications in the name of the Company, for permits, registrations and other governmental authorizations, relating in any way to the quality assurance, quality control, regulatory, warehousing, distribution, licensing, and sterilizing functions of the Company, and to represent the Company and take all necessary actions in legal matters and all other matters towards all third parties and all public authorities, federal, state or municipal, and towards all other divisions, subdivisions, departments, units or all secretariats of the above, relating in any way to the quality assurance, quality control, regulatory, warehousing, distribution, licensing, and sterilizing functions of the Company.

This Power of Attorney is valid until revoked in writing by the Company.

Dated: January 21, 2026

Medline Industries, LP
By: Mozart GP, LLC
Its: General Partner

By: _____
Name: Alexander M. Liberman
Title: Chief Legal Officer and Secretary

ACKNOWLEDGEMENT

STATE OF ILLINOIS
COUNTY OF COOK

This instrument was acknowledged before me on January 21, 2026 by Alexander M. Liberman, as Chief Legal Officer and Secretary of Mozart GP, LLC, as General Partner of Medline Industries, LP.

_____
(Signature of Notary Public) (Seal)

OFFICIAL SEAL
Barbara Theresa Bychowski
NOTARY PUBLIC, STATE OF ILLINOIS
Commission No. 1016211
My Commission Expires August 28, 2029

Attachment 8

NABP ACCREDITED
DRUG DISTRIBUTOR

Medline Industries, LP

located at

21111 E. 36th Dr, Aurora, CO 80011

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

12/06/2023 - 12/05/2026
Period of Accreditation

Medline Industries, LP

FEIN: 36-2596612
An Illinois Limited Partnership

Contact Information:

Three Lakes Drive
Attn: RA Licensing – 3D
Northfield, IL 60093
Ralicensing@medline.com
847-949-5500

Partners:

Partner	General or Limited	Business Address	% of Ownership	FEIN
Medline Borrower, LP	Limited	Three Lakes Drive, Northfield, IL 60093	100%	87-2530238
Mozart GP, LLC	General	Three Lakes Drive, Northfield, IL 60093	0%	87-2508203

Officers of General Partner - Mozart GP, LLC:

Name	Title	Home Address	SSN	DOB
James M. Boyle	Chief Executive Officer	[redacted]		
Stephen L. Miller	Chief Operating Officer			
Michael B. Drazin	Chief Financial Officer			
Alexander M. Liberman	General Counsel, Secretary			

Attachment 2

Medline Inc.

FEIN: IL 33-185288

Contact Information:
3 Lakes Drive
Attn: RA Licensing – 3D
Northfield, IL 60093
Ralicensing@medline.com
847-949-5500

Officers and Directors:
Information as of 07/09/2026

Officers

Name	Title
James M. Boyle	Chief Executive Officer
Michael B. Drazin	Chief Financial Officer
Stephen L. Miller*	Chief Operating Officer
Alexander M. Liberman	Chief Legal Officer
Douglas P. Golwas	Chief Commercial Officer
Christopher P. Shryock	Chief Human Resources Officer
Amanda Hutton Laabs	Chief Product Officer
Jessi Corcoran	Chief Accounting Officer
William J. Abrams	Executive Vice President, Supply Chain Solutions

*On July 7, 2026, Stephen L. Miller, Chief Operating Officer of Medline Inc. (the "Company"), notified the Company that he would retire from his role, effective August 30, 2026/ The Company is launching a search for his successor.

Directors

Name	Title
Charles N. Mills	Non-Executive Chair of the Board
Andrew J. Mills	Director
Anushka M. Sunder	Director
Jacob D. Best	Director
James M. Boyle	Director
Joseph P. Baratta	Director
Patrick J. Healy	Director
Richard A. Galanti	Director
Robert R. Schmidt	Director
Stephen H. Wise	Director
Thomas W. Sweet	Director
Todd N. Bluedorn	Director

Attachment 3

Medline Inc.
Top Four Shareholders

Medline Inc.
Medline Inc. is a U.S. publicly traded company trading under the ticker symbol MDLN on Nasdaq. Medline Inc. publicly reports beneficial holders of 5% or more of its outstanding securities ("significant stockholders") in its filings with the U.S. Securities and Exchange Commission ("SEC"), which are available at www.sec.gov/edgar/browse/?CIK=2046386. Medline Inc. reports this information in accordance with SEC rules, including in reliance on public reporting of ownership by its significant stockholders.

Top Four Shareholders of Medline Inc. as of May 4, 2026

Name of Beneficial Owner	Combined Voting Power
Mozart HoldCo, Inc.[1]	17.8%
Blackstone[2]	14.2%
Carlyle[3]	14.2%
H&F[4]	14.2%

[1] Mozart HoldCo, Inc. is an entity that is owned directly and/or indirectly by members of the Mills Family and trusts for their benefit.
[2] "Blackstone" refers to certain entities and/or funds associated with Blackstone Inc.
[3] "Carlyle" refers to certain entities and/or funds associated with The Carlyle Group Inc.
[4] "H&F" refers to certain entities and/or funds associated with Hellman & Friedman LLC

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "MEDLINE INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRD DAY OF APRIL, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "MEDLINE INC." WAS INCORPORATED ON THE SIXTH DAY OF NOVEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. J. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5143163 8300

SR# 20261572157

Authentication: 203550646

Date: 04-03-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

Attachment 4

File Number S030704

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias,** *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

MEDLINE INDUSTRIES, LP, HAVING REGISTERED IN THE STATE OF ILLINOIS ON SEPTEMBER 07, 2021, APPEARS TO HAVE COMPLIED WITH ALL PROVISIONS OF THE UNIFORM LIMITED PARTNERSHIP ACT (2001) OF THIS STATE, AND AS OF THIS DATE IS IN GOOD STANDING AS A DOMESTIC LP/LLLP IN THE STATE OF ILLINOIS, HAVING FULFILLED ALL REQUIREMENTS OF SAID ACT WITH REGARD TO PAYMENT OF FEES, THE FILING OF ANNUAL REPORTS (IF APPLICABLE) AND NEITHER HAVING BEEN ADMINISTRATIVELY DISSOLVED BY THE SECRETARY OF STATE NOR HAVING VOLUNTARILY FILED A STATEMENT OF TERMINATION.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 15TH *day of* APRIL *A.D.* 2026 .

SEAL OF THE STATE OF ILLINOIS — UNION — NATIONAL — SOVEREIGNTY — STATE — 1868 1818 — AUG. 26TH 1818

Authentication #: 2610502528 verifiable until 04/15/2027
Authenticate at: https://www.ilsos.gov

Alexi Giannoulias
SECRETARY OF STATE

OFFICE OF THE SECRETARY OF STATE
OF THE STATE OF COLORADO

CERTIFICATE OF FACT OF GOOD STANDING

I, Jena Griswold, as the Secretary of State of the State of Colorado, hereby certify that, according to the records of this office,

Medline Industries, LP

is an entity formed or registered under the law of Illinois has complied with all applicable requirements of this office, and is in good standing with this office. This entity has been assigned entity identification number 20061493118 .

This certificate reflects facts established or disclosed by documents delivered to this office on paper through 08/10/2026 that have been posted, and by documents delivered to this office electronically through 08/11/2026 @ 12:35:11 .

I have affixed hereto the Great Seal of the State of Colorado and duly generated, executed, and issued this official certificate at Denver, Colorado on 08/11/2026 @ 12:35:11 in accordance with applicable law. This certificate is assigned Confirmation Number 18892787 .

Jena Griswold

Secretary of State of the State of Colorado

**********End of Certificate**********

Notice: A certificate issued electronically from the Colorado Secretary of State's website is fully and immediately valid and effective. However, as an option, the issuance and validity of a certificate obtained electronically may be established by visiting the Validate a Certificate page of the Secretary of State's website, https://www.coloradosos.gov/biz/CertificateSearchCriteria.do entering the certificate's confirmation number displayed on the certificate, and following the instructions displayed. Confirming the issuance of a certificate is merely optional and is not necessary to the valid and effective issuance of a certificate. For more information, visit our website, https://www.coloradosos.gov click "Businesses, trademarks, trade names" and select "Frequently Asked Questions."

Attachment 7

COLORADO
Department of Regulatory Agencies
Division of Professions and Occupations

Below are your electronic wallet cards to use as proof of your license. You can also print your license at any time by visiting www.colorado.gov/dora/DPO_Print_License and following the instructions listed.

If you would like a more durable wallet card option, you can order one for a fee by visiting www.nasbastore.org and selecting the "Colorado License Cards" link on the left hand side of the page. If you prefer, you can also contact NASBA by phone at 1-888-925-5237 or by email at nasbastore@nasba.org.

Should you have questions about your credential, or need other information please contact our Customer Service Team at 303-894-7800 or dora_dpo_licensing@state.co.us.

Colorado Department of Regulatory Agencies
Division of Professions and Occupations

State Board of Pharmacy
Medline Industries, LP

Wholesaler In-State

WHI.0006110	11/01/2024
Number	**Issue Date**
Active	10/31/2026
Credential Status	**Expire Date**

Verify this credential at: dpo.colorado.gov

Division Director: Sam Delp | Credential Holder Signature

Colorado Department of Regulatory Agencies
Division of Professions and Occupations

State Board of Pharmacy
Medline Industries, LP

Wholesaler In-State

WHI.0006110	11/01/2024
Number	**Issue Date**
Active	10/31/2026
Credential Status	**Expire Date**

Verify this credential at: dpo.colorado.gov

Division Director: Sam Delp | Credential Holder Signature

Lookup Detail View

Licensee Information

This serves as primary source verification of the license.*

**Primary source verification: License information provided by the Colorado Division of Professions and Occupations, established by 24-34-102 C.R.S.*

Name	DBA	Public Address
Medline Industries, LP		21111 E 36th Dr Aurora, CO 80011-8193

Credential Information

License Number	License Method	License Type	License Status	Original Issue Date	Effective Date	Expiration Date
WHI.0006110	Original	Wholesaler In-State	Active	04/16/2017	11/01/2024	10/31/2026

Board/Program Actions

Discipline
There is no Discipline or Board Actions on file for this credential.

Generated on: 8/11/2026 1:01:07 PM

Attachment 9

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 06/22/2026

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

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

PRODUCER MARSH USA LLC. 155 N. WACKER, SUITE 1200 CHICAGO, IL 60661 CN101705524-Stnd-GAWUP-26-27 USA	**CONTACT NAME:** Medline Industries, LP **PHONE (A/C, No, Ext):** **FAX (A/C, No):** **E-MAIL ADDRESS:** riskmanagement@medline.com
INSURED Medline Industries, LP 3 Lakes Dr Northfield, IL 60093	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** Safety National Casualty Corporation — 15105 **INSURER B :** Endurance Assurance Corporation — 11551 **INSURER C :** See Acord 101 for Carrier Participation **INSURER D :** **INSURER E :** **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** CHI-008956355-45 **REVISION NUMBER:** 80

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X **COMMERCIAL GENERAL LIABILITY** CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC OTHER:			GL 4065036	07/01/2026	07/01/2027	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 2,000,000 $ 2,000,000 $ 10,000 $ 2,000,000 $ 4,000,000 $ SEE BELOW
A	**AUTOMOBILE LIABILITY** X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			CA 6675933	07/01/2026	07/01/2027	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 2,000,000 $ $ $
B	X **UMBRELLA LIAB** X OCCUR **EXCESS LIAB** CLAIMS-MADE DED X RETENTION $ 10,000			ELD10004065213	07/01/2026	07/01/2027	EACH OCCURRENCE AGGREGATE	$ 10,000,000 $ 10,000,000
A A	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [Y] N/A **(Mandatory in NH)** If yes, describe under DESCRIPTION OF OPERATIONS below			LDS 4065032 (AOS) PS 4065034 (WI)	07/01/2026 07/01/2026	07/01/2027 07/01/2027	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
C	Products/Completed Operations Liability			LSR-PCO-00678-26	07/01/2026	07/01/2027	Limit	2,000,000

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

Re: C42 - 3446 Highway 51 N Southaven, MS 38672. C40- 81 Campanelli Dr, Uxbridge, MA 01569.

SIR applies per policy terms & conditions. The products/completed operations policy evidenced above is subject to self-insured retentions for various perils covered.

Evidence of Insurance.

CERTIFICATE HOLDER

Medline Industries, LP
3 Lakes Dr.
Northfield, IL 60093

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Marsh USA Inc.

© 1988-2016 ACORD CORPORATION. All rights reserved.

AGENCY CUSTOMER ID: CN101705524

LOC #: Chicago

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC.	Medline Industries, LP 3 Lakes Dr Northfield, IL 60093
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

LOCATION ADDRESS CITY STATE ZIP CODE

B01 1 Medline Pl. Mundelein Illinois 60060
B04 1160 S Northpoint Blvd S . Waukegan Illinois 60085
B04 1710 S Lakeside Dr. Waukegan Illinois 60085
B04 1170 S Northpoint Blvd S. Waukegan Illinois 60085
B06 1 Medline Dr. Wilmer Texas 75172
B11 21111 E 36th Dr. Aurora Colorado 80011
B18 1062 Fasken Blvd. Laredo Texas 78045
B22 9670 NW 112 Ave. Medley Florida 33178
B24 8001 SW 47th St. Oklahoma City Oklahoma 73179
B25 1401 N Universal Ave. Kansas City Missouri 64120
B27 92 SE 223rd Ave. Gresham Oregon 97030
B28 735 County Rd 4 E. Prattville Alabama 36067
B29 13115 Brockton Lane N. Rogers Minnesota 55374
B30 1900 Meadowville Technology Parkway. Chester Virginia 23836
B31 500 Sharkey Dr. Maumelle Arkansas 72113
B34 9051 King St. Anchorage Alaska 99518
B36 1989 Transit Way, Brockport New York 14420
B44 2325 W Louise Ave. Manteca California 95337
B45 1119 W Middlesex Ave Bldg 4. Port Reading New Jersey 07064
B48 36445 Van Born Road, Suite 200 Romulus Michigan 48174
B49 42500 Winchester Rd. Temecula California 92590
B56 190 Medline Drive, Suite 200. Richmond Hill Georgia 31324
B66 2700 E. Imperial Highway Lynwood California 90262
B80 2341 Lauwiliwili St, Suite 107 Kapolei Hawaii 96707
B82 9103 Riverside Parkway Lithia Springs Georgia 30122
C02 2200 Cornerstone Parkway. Grayslake Illinois 60030
C03 1500 Medline Pl. McDonough Georgia 30253
C05 1062 Old Dixie Highway. Auburndale Florida 33823
C09 1960 W Miro Way. Rialto California 92376
C32 29895 US Hwy 90 Bus. Katy Texas 77494
C37 5000 Premier Parkway. St. Peters Missouri 63376
C40 81 Campanelli Dr. Uxbridge Massachusetts 01569
C41 1040 Enterprise Parkway South. West Jefferson Ohio 43162
C42 3446 Highway 51 N. Southaven Mississippi 38672
C46 5701 Promontory Parkway, Suite 100 Tracy California 95377
C47 239 Belvidere Rd. Perryville Maryland 21903
C50 8787 W Buckeye Ave. Tolleson Arizona 85353
C54 494 State Route 416. Montgomery New York 12549
C57 5511 W Ten Rd. Mebane North Carolina 27302
C59 2100 Industrial Park Road Hammond Louisiana 70401
C71 264 S 5750 W. Salt Lake City Utah 84104
C75 3770 Hogum Bay Rd NE. Lacey Washington 98516
C89 251 Hilton Dr. Jeffersonville Indiana 47130
RCH - Hartland, WI 700 W North Shore Dr. Hartland Wisconsin 53029
D46 - Lathrop, CA 18601 Christopher Way Ste 100. Lathrop California 95330
MXC - SPT 16415 Cosmos St. Moreno Valley California 92551
ANGIO 10 Glen Falls Technical Park. Glen Falls New York 12801
E22 600 Derby Ave West Haven Connecticut 06516
E23 3835 John Wall Dr Madison Wisconsin 53704

© 2008 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: CN101705524
LOC #: Chicago

ACORD®

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC.	Medline Industries, LP 3 Lakes Dr Northfield, IL 60093
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

E26 1390 Sparrows Point Blvd Ste700 Edgemere Maryland 21219
LRD 12001 General Milton Dr. Laredo Texas 78045

© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Medline Industries, LP MDEG License # (if applicable) _____

Physical Address 21111 E. 36th Dr.

City Aurora State CO Zip 80011

Mailing Address (if different from physical address) Three Lakes Drive - 3D

City Northfield State IL Zip 60093

Telephone 847-643-3801 Website www.medline.com

Licensing Company Email ralicensing@medline.com

Section 2: Personal Information

First Angelica Middle Jeanea Last Chavez

Alias(es, nicknames, name changes, etc.) Angelica Chavez - Reep

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

Mailing Addre[redacted]

City Denver State CO Zip [redacted]

Telephone [redacted] Email achavez@medline.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Pacific High School		06/98 - 06/02	
Address	**City**	**State**	**Zip**
1020 Pacific St.	San Bernardino	CA	92404
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/24 - Present	[redacted]	Denver	CO	[redacted]
2013 - 06/24		San Bernardino	CA	
From - To (MM/YY – MM/YY)	Address	City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Medline Industries, LP			06/24 - Present	
Business Address		**City**	**State**	**Zip**
21111 E. 36th Dr.		Aurora	CO	80011
Phone	**Title**		**Number of Employed Hours**	
303-371-8546	Director of Operations		4,560 +	
Description of Duties				
Oversee the facility to ensure proper receiving, distribution, storage, shipping and dispensing of prescription drugs and medical devices. Manage multiple team members to ensure proper record keeping, inventory, storage and product security.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Angelica Chavez Beep
Original Signature (electronic, copies or stamps not accepted)

7/22/26
Date

I, Angelica Chavez, **certify that as the MDEG Administrator for**

Medline Industries, LP,

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

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

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

Angelica, Chavez
Print Name (First, Last)

Angelica Chavez Beep
Original Signature (electronic, copies or stamps not accepted)

7/22/26
Date

Board Use Only	Date Received: 8/7/26

Attachment 6

Medline - Aurora, CO - Employee List

First Name	Last Name	Primary Location
Berhanu	Chimsa	OPS- Aurora, CO B11
Kaylee	Fisher	OPS- Aurora, CO B11
Jesus	Velasco	OPS- Aurora, CO B11
Melfen	Jacob	OPS- Aurora, CO B11
George	Braun	OPS- Aurora, CO B11
Nicholas	Hill-traylor	OPS- Aurora, CO B11
Nadou	Lawson	OPS- Aurora, CO B11
Zewdu	Desta	OPS- Aurora, CO B11
Hector	Bracamontes	OPS- Aurora, CO B11
Awudu	Fuseini	OPS- Aurora, CO B11
Nain	Perez	OPS- Aurora, CO B11
Joel	Bravo	OPS- Aurora, CO B11
Mewae	Gebremariam	OPS- Aurora, CO B11
Melina	Rios	OPS- Aurora, CO B11
River	Macias	OPS- Aurora, CO B11
Brian	Serrano	OPS- Aurora, CO B11
Jacob	Herron	OPS- Aurora, CO B11
Than	Tran	OPS- Aurora, CO B11
Eugene	Bisungu	OPS- Aurora, CO B11
Yohana	Mendiola	OPS- Aurora, CO B11
Robin	Zelaya	OPS- Aurora, CO B11
Reynaldo	Villalpando	OPS- Aurora, CO B11
Deshawn	Vaughns	OPS- Aurora, CO B11
Oriana	Shephard	OPS- Aurora, CO B11
Tarah	Apachito	OPS- Aurora, CO B11
Frederick	Pinkston	OPS- Aurora, CO B11
Oyenitiwa	Attivi	OPS- Aurora, CO B11
Connor	Dietz	OPS- Aurora, CO B11
Eva	Roberts	OPS- Aurora, CO B11
Patrick	Franklin	OPS- Aurora, CO B11
Nikolas	Buergin	OPS- Aurora, CO B11
Yosef	Yilma	OPS- Aurora, CO B11
Terrell	Mccrary	OPS- Aurora, CO B11
Manuel	Jaquez	OPS- Aurora, CO B11
Collins	Adjei	OPS- Aurora, CO B11
Jose	Gomez	OPS- Aurora, CO B11
Curtis	Boothe	OPS- Aurora, CO B11
Kourtney	Santos	OPS- Aurora, CO B11
William	Bahena	OPS- Aurora, CO B11
Maurion	Cortez	OPS- Aurora, CO B11
Corey	Burris	OPS- Aurora, CO B11
Crassus	Conquest	OPS- Aurora, CO B11
Miguel	Bravo	OPS- Aurora, CO B11
Broderick	Scott	OPS- Aurora, CO B11
Markiese	Short	OPS- Aurora, CO B11
James	Berrigan	OPS- Aurora, CO B11

Charles	Thompson	OPS- Aurora, CO B11
Ricardo	Shephard	OPS- Aurora, CO B11
Amanda	Aguillard	OPS- Aurora, CO B11
Peter	Owusu	OPS- Aurora, CO B11
Jonathan	Coates	OPS- Aurora, CO B11
Luis	Serrano	OPS- Aurora, CO B11
Rashaad	Nguyen	OPS- Aurora, CO B11
Skyeler	Stayton	OPS- Aurora, CO B11
Vanesa	Salamanca	OPS- Aurora, CO B11
Rodrigo	Alonso	OPS- Aurora, CO B11
Jayd	Willis	OPS- Aurora, CO B11
Jaime	Castillo	OPS- Aurora, CO B11
Jacqueline	Afriyie	OPS- Aurora, CO B11
Trevor	Rogers	OPS- Aurora, CO B11
Michael	Baker	OPS- Aurora, CO B11
Jessica	Pineda	OPS- Aurora, CO B11
Gabriel	Kotilo	OPS- Aurora, CO B11
Jonathan	Nguyen	OPS- Aurora, CO B11
Jeremy	Harris	OPS- Aurora, CO B11
Manuel	Loya-saenz	OPS- Aurora, CO B11
Devonte	Villarreal	OPS- Aurora, CO B11
Santiago	Anguizola	OPS- Aurora, CO B11
Alex	Okyere	OPS- Aurora, CO B11
Steven	White	OPS- Aurora, CO B11
Angel	Gutierrez	OPS- Aurora, CO B11
Jose	Lisardo	OPS- Aurora, CO B11
Alisha	Brown	OPS- Aurora, CO B11
Michael	Hargrave	OPS- Aurora, CO B11
Cerlon	Longino	OPS- Aurora, CO B11
Derrick	Dock	OPS- Aurora, CO B11
Yvette	Uwamahoro	OPS- Aurora, CO B11
Aarron	Stevenson	OPS- Aurora, CO B11
Lakeasha	Hill	OPS- Aurora, CO B11
Paul	Lange	OPS- Aurora, CO B11
Jean David	Milord	OPS- Aurora, CO B11
David	Valdez	OPS- Aurora, CO B11
Alejandro	Cabral Gonzalez	OPS- Aurora, CO B11
William	Wall	OPS- Aurora, CO B11
Danae	Pacheco	OPS- Aurora, CO B11
Fernando	Duenas Alvarez	OPS- Aurora, CO B11
Matthew	Vass	OPS- Aurora, CO B11
Kassandra	Martinez	OPS- Aurora, CO B11
Katib	Korok	OPS- Aurora, CO B11
Robert	Conner	OPS- Aurora, CO B11
Christopher	Jamison	OPS- Aurora, CO B11
Jacob	Thornton	OPS- Aurora, CO B11
Cassie	Barta	OPS- Aurora, CO B11
Kevin	Nicolas-marmolejo	OPS- Aurora, CO B11
Alexander	Reid	OPS- Aurora, CO B11
Alejandro	Ruiz	OPS- Aurora, CO B11

Tanija	Sharpe	OPS- Aurora, CO B11
Adrian	Clark	OPS- Aurora, CO B11
Ervin	Ruiz	OPS- Aurora, CO B11
Ernest	Daniels	OPS- Aurora, CO B11
Corey	Dixson	OPS- Aurora, CO B11
Amy	Arias	OPS- Aurora, CO B11
Elijah	Smith	OPS- Aurora, CO B11
Steven	Mendoza Gutierrez	OPS- Aurora, CO B11
Ignacio	Trejo	OPS- Aurora, CO B11
Karina	Perez	OPS- Aurora, CO B11
Juan	Reyes	OPS- Aurora, CO B11
Jameelah	Edwards	OPS- Aurora, CO B11
Shakila	Akbari	OPS- Aurora, CO B11
Dustin	Messner	OPS- Aurora, CO B11
Jorge	Ortiz	OPS- Aurora, CO B11
Randy	Jager	OPS- Aurora, CO B11
Javier	Alvarez Rivera	OPS- Aurora, CO B11
Raymond	Morris	OPS- Aurora, CO B11
Flynn	Yancey	OPS- Aurora, CO B11
Emmanuel	Hayford	OPS- Aurora, CO B11
Kalan	Nelson	OPS- Aurora, CO B11
Joshua	Carr	OPS- Aurora, CO B11
Gerardo	Rosales Hernandez	OPS- Aurora, CO B11
Guadalupe	Soto Benitez	OPS- Aurora, CO B11
Lawrence	Lynn	OPS- Aurora, CO B11
Charles	Aryee	OPS- Aurora, CO B11
Cesar	Chavez Basquez	OPS- Aurora, CO B11
Akeem	Gardner	OPS- Aurora, CO B11
Qiuanna	Mingo	OPS- Aurora, CO B11
Anthony	Bueno	OPS- Aurora, CO B11
Josephine	Longaker	OPS- Aurora, CO B11
Ivan	Victoria	OPS- Aurora, CO B11
Paula	Smith	OPS- Aurora, CO B11
Gerald	Miller	OPS- Aurora, CO B11
Alejandro	Fong	OPS- Aurora, CO B11
Mikayla	Amos	OPS- Aurora, CO B11
Samuel	Kyeremanteng	OPS- Aurora, CO B11
Tajhae	Darden	OPS- Aurora, CO B11
Kelli	Quintana	OPS- Aurora, CO B11
Sarah	Perez	OPS- Aurora, CO B11
James	Mills	OPS- Aurora, CO B11
Paul	Dawan	OPS- Aurora, CO B11
Larry	Castro	OPS- Aurora, CO B11
Linda	Agyemang	OPS- Aurora, CO B11
Antonio	Long	OPS- Aurora, CO B11
Shari	Cordova	OPS- Aurora, CO B11
Jose	Hernandez	OPS- Aurora, CO B11
Marvin	Hamilton	OPS- Aurora, CO B11
Ashley	Valenzuela	OPS- Aurora, CO B11
Eliseo	Villarreal	OPS- Aurora, CO B11

Jesse	Riley	OPS- Aurora, CO B11
Robert	Manlove	OPS- Aurora, CO B11
General	Lundy	OPS- Aurora, CO B11
Zion	Wilson	OPS- Aurora, CO B11
Scott	Grenoble	OPS- Aurora, CO B11
Emmanuel	Appiah	OPS- Aurora, CO B11
Joseph	Duran	OPS- Aurora, CO B11
Kayr	Rosario	OPS- Aurora, CO B11
Kimberly	Guzman	OPS- Aurora, CO B11
Shantavia	Braxton	OPS- Aurora, CO B11
Christopher	Stroh	OPS- Aurora, CO B11
Julio	Valle	OPS- Aurora, CO B11
Nigel	Hicks	OPS- Aurora, CO B11
Collin	Cordova	OPS- Aurora, CO B11
Kasean	Smith	OPS- Aurora, CO B11
Phillip	Mcneely	OPS- Aurora, CO B11
Dennis	Corbin	OPS- Aurora, CO B11
Sharon	Watson	OPS- Aurora, CO B11
Kyle	Hernandez	OPS- Aurora, CO B11
Rose	Cordova	OPS- Aurora, CO B11
Mercedes	Plazola	OPS- Aurora, CO B11
Brandon	Robinson	OPS- Aurora, CO B11
Jaiire	Pearson	OPS- Aurora, CO B11
Sampson	Adjei	OPS- Aurora, CO B11
Miguel	Camacho	OPS- Aurora, CO B11
Edgar	Quintana	OPS- Aurora, CO B11
Francis	Aboagye	OPS- Aurora, CO B11
Joshua	Fey	OPS- Aurora, CO B11
Rich-leue	Mants	OPS- Aurora, CO B11
Arthur	Anderson	OPS- Aurora, CO B11
Bryan	Canady	OPS- Aurora, CO B11
Jack	Kirkland	OPS- Aurora, CO B11
Tykim	Matthews	OPS- Aurora, CO B11
Dwayne	Francis	OPS- Aurora, CO B11
Landen	Aprill	OPS- Aurora, CO B11
Zykelyus	Hawkins	OPS- Aurora, CO B11
Nicole	Jenkins	OPS- Aurora, CO B11
Sergio	Alarid	OPS- Aurora, CO B11
Brian	Stavrou	OPS- Aurora, CO B11
Olivia	Kalenge	OPS- Aurora, CO B11
Andre	Hutchison	OPS- Aurora, CO B11
Neema	Masuku	OPS- Aurora, CO B11
Joy	Ward	OPS- Aurora, CO B11
Kiana	Williams	OPS- Aurora, CO B11
Tais	Hall	OPS- Aurora, CO B11
Melissa	Castillo	OPS- Aurora, CO B11
Cory	Chevarria	OPS- Aurora, CO B11
Pavis	Zanubon	OPS- Aurora, CO B11
Betania	Suarez	OPS- Aurora, CO B11
Ashley	Renteria	OPS- Aurora, CO B11

Angel	Hildebrand	OPS- Aurora, CO B11
David	Alvarez	OPS- Aurora, CO B11
Ismenia	Ventura	OPS- Aurora, CO B11
Ciera	Quick	OPS- Aurora, CO B11
Lonnie	Suber	OPS- Aurora, CO B11
David	Eustace	OPS- Aurora, CO B11
Anthony	Hunter	OPS- Aurora, CO B11
Mahmood	Mahmoodi	OPS- Aurora, CO B11
Yaw	Amoateng	OPS- Aurora, CO B11
Steven	Juris	OPS- Aurora, CO B11
Jhovana	Mora	OPS- Aurora, CO B11
Derek	Pacheco	OPS- Aurora, CO B11
Telisha	Brown	OPS- Aurora, CO B11
Michelle	Abeyta	OPS- Aurora, CO B11
Darren	Rowe	OPS- Aurora, CO B11
Oziel	Ramirez	OPS- Aurora, CO B11
Jayhsan	Rodriguez	OPS- Aurora, CO B11
Tania	Gurrola Pompa	OPS- Aurora, CO B11
Roxanne	Rieske	OPS- Aurora, CO B11
Raheem	Matlock	OPS- Aurora, CO B11
Nelson	Jones	OPS- Aurora, CO B11
Brady	Baltazar	OPS- Aurora, CO B11
Gary	Garcia Mendez	OPS- Aurora, CO B11
Jarrod	Hachez	OPS- Aurora, CO B11
Belkis	Ocampo	OPS- Aurora, CO B11
William	Engborg	OPS- Aurora, CO B11
Jamnab	Oul	OPS- Aurora, CO B11
Lorenzo	Olivas	OPS- Aurora, CO B11
Boima	Sonii	OPS- Aurora, CO B11
Joy	Mabry	OPS- Aurora, CO B11
Leslie	Nash	OPS- Aurora, CO B11
Eric	Stapp	Aurora, CO B11
Major	Gallimore	OPS- Aurora, CO B11
James	Sprinkel	Aurora, CO B11
Ana	Castillo	OPS- Aurora, CO B11
Robert	Wright	OPS- Aurora, CO B11
Randy	Nichols	OPS- Aurora, CO B11
Robert	Mccotter	OPS- Aurora, CO B11
Jon-paul	Boisvert	OPS- Aurora, CO B11
Lorena	David	OPS- Aurora, CO B11
Rowel	David	OPS- Aurora, CO B11
Christine	Perez	OPS- Aurora, CO B11
Shimels	Fentaw	Aurora, CO B11
Zachery	Asher	OPS- Aurora, CO B11
Anthony	White	OPS- Aurora, CO B11
James	Jenkins	Aurora, CO B11
Quortavious	Dent	Aurora, CO B11
Jared	Cephus	Aurora, CO B11
Jesenia	Izaguirre	Aurora, CO B11
Esther	Nabauk	Aurora, CO B11

Paul	Smith	OPS- Aurora, CO B11
Luwabar	Kuma-kuma	OPS- Aurora, CO B11
Sonia	Fuentes	OPS- Aurora, CO B11
Isaac	Streib	OPS- Aurora, CO B11
Kenneth	Barela	OPS- Aurora, CO B11
Griselda	Barrera	Aurora, CO B11
Danny	Yakhason	OPS- Aurora, CO B11
Isela	Brunner	OPS- Aurora, CO B11
Ayaliew	Ambaw	OPS- Aurora, CO B11
Berenice	Castillo	OPS- Aurora, CO B11
Jarvis	Lee	OPS- Aurora, CO B11
Ayantu	Etefa	OPS- Aurora, CO B11
Bruce	Phillips	Aurora, CO B11
Liliana	Solis	OPS- Aurora, CO B11
William	Linares	Aurora, CO B11
Melvin	Buchanan	OPS- Aurora, CO B11
Jesus	Gonzalez	Aurora, CO B11
Majaliwa	Kabandelwa	OPS- Aurora, CO B11
David	Simon	OPS- Aurora, CO B11
Deborah	Garcia	Aurora, CO B11
Michael	Alty	OPS- Aurora, CO B11
Xitlaly	Valladares	OPS- Aurora, CO B11
Colin	Wilstead	Aurora, CO B11
Heydi	Martinez Fuentes	OPS- Aurora, CO B11
Ashanti	Cato	OPS- Aurora, CO B11
Nicholas	Villalobos	Aurora, CO B11
Angel	Valerio	Aurora, CO B11
Hector	Mares	OPS- Aurora, CO B11
Alimata	Ouedraogo	OPS- Aurora, CO B11
Bryan	Arenas	OPS- Aurora, CO B11
Jhonatan	Diaz Miguel	Aurora, CO B11
Samuel	Rubio	Aurora, CO B11
Martha	Felix	OPS- Aurora, CO B11
Manuel	Chiquito	Aurora, CO B11
Luis	Manzanares	OPS- Aurora, CO B11
Erik	Fenney	Aurora, CO B11
James	Helkena	OPS- Aurora, CO B11
Iginace	Nsabimana	OPS- Aurora, CO B11
Ariana	Coria	Aurora, CO B11
Christian	Ilunga	OPS- Aurora, CO B11
Mario	Cruz	OPS- Aurora, CO B11
Carla	Romero	OPS- Aurora, CO B11
Aicha	Ouedraogo	OPS- Aurora, CO B11
Ryan	Fullenwider	OPS- Aurora, CO B11
Roberto	Castillo	OPS- Aurora, CO B11
David	Duenas	Aurora, CO B11
Angelina	Ansu	OPS- Aurora, CO B11
Robert	Macias	OPS- Aurora, CO B11
Emanuel	Castillo Perez	OPS- Aurora, CO B11
Peter	Clark	OPS- Aurora, CO B11

Michael	Wright	OPS- Aurora, CO B11
Jada	Porter	OPS- Aurora, CO B11
Eric	Vasquez	OPS- Aurora, CO B11
Brock	Pedersen	OPS- Aurora, CO B11
Curtis	Hayes	OPS- Aurora, CO B11
David	Hodge	OPS- Aurora, CO B11
Emon	Mitchell	Aurora, CO B11
Dustin	Mcintosh	OPS- Aurora, CO B11
Wyatt	Fisher	OPS- Aurora, CO B11
Jorge	Aponte Rodriguez	OPS- Aurora, CO B11
Alondra	Resendiz Sierra	OPS- Aurora, CO B11
Giovanni	Ortega	Aurora, CO B11
Carlos	Rojas	OPS- Aurora, CO B11
Anthony	Mcintyre	OPS- Aurora, CO B11
Edgar	Castorena	OPS- Aurora, CO B11
Kellen	Bryant	OPS- Aurora, CO B11
Cole	Hoover	OPS- Aurora, CO B11
Keith	Robinson	OPS- Aurora, CO B11
Eva	Briones Ruiz	OPS- Aurora, CO B11
Pamela	Yombo	Aurora, CO B11
Jose	Burgos	Aurora, CO B11
Befkadu	Kelbore	OPS- Aurora, CO B11
Vina Amor	Meidinger	OPS- Aurora, CO B11
Angelica	Chavez	OPS- Aurora, CO B11
Alyse	Gordon	OPS- Aurora, CO B11
Allison	O'connell	OPS- Aurora, CO B11
Adriel	Ross	OPS- Aurora, CO B11
Brian	Anzures	OPS- Aurora, CO B11
Brian	Grano	OPS- Aurora, CO B11
Benjamin	Waite	OPS- Aurora, CO B11
Bridget	Meyer	OPS- Aurora, CO B11
Brittany	Phillips	OPS- Aurora, CO B11
Charlie	Andablo	OPS- Aurora, CO B11
Christopher	Lamson	OPS- Aurora, CO B11
Colin	Quinn	OPS- Aurora, CO B11
Christopher	Stone	OPS- Aurora, CO B11
Devin	Kelly-meyer	OPS- Aurora, CO B11
Dannika	Johnson	OPS- Aurora, CO B11
Dorian	Settles	OPS- Aurora, CO B11
Hector	Fabela	OPS- Aurora, CO B11
Hortencia	Leal Bustillos	OPS- Aurora, CO B11
Jaqueline	Guzman	OPS- Aurora, CO B11
Jacob	Fuhrman	Aurora, CO B11
James	Garcia	OPS- Aurora, CO B11
James	Johnston	OPS- Aurora, CO B11
Jihad	Mujib	OPS- Aurora, CO B11
James	Dillon	OPS- Aurora, CO B11
Johnathan	Wilhelm	OPS- Aurora, CO B11
Kevin	Young	OPS- Aurora, CO B11
Katia	Parkin	OPS- Aurora, CO B11

Luis	Hernandez	OPS- Aurora, CO B11
Larry	Snider	OPS- Aurora, CO B11
Mario	Gutierrez	OPS- Aurora, CO B11
Marvin	Johnson	OPS- Aurora, CO B11
Morgan	Haddock	OPS- Aurora, CO B11
Maria	Flores	OPS- Aurora, CO B11
Mario	Rodriguez-vega	OPS- Aurora, CO B11
Nancy	Benitez	OPS- Aurora, CO B11
Paul	Deleon	Aurora, CO B11
Pleasure	Ellis	OPS- Aurora, CO B11
Ruth	Ramirez	OPS- Aurora, CO B11
Steven	Clifford	OPS- Aurora, CO B11
Sandra	Gomez	OPS- Aurora, CO B11

Attachment 5

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 001-43022

Medline Inc.

(Exact name of registrant as specified in its charter)

Delaware	**33-1845288**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3 Lakes Drive Northfield, Illinois	**60093**
(Address of principal executive offices)	(Zip Code)

(847) 949 5500
Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, par value $0.0001 per share	MDLN	Nasdaq Global Select Market

Securities registered pursuant to section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☐ No ☒

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ☐ No ☒

The aggregate market value of the Class A common stock held by non-affiliates of the registrant, based on the closing price of a share of Class A common stock on December 17, 2025, as reported by The Nasdaq Global Select Market on such date was approximately $13.0 billion. The registrant has elected to use December 17, 2025, which was the initial trading date of the registrant's Class A common stock on The Nasdaq Global Select Market, as the calculation date because on June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter) the registrant was a privately held company. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of February 23, 2026, there were 811,647,534 shares of the registrant's Class A common stock and 502,045,878 shares of the registrant's Class B common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement related to its 2026 Annual Meeting of Stockholders to be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year ended December 31, 2025 are incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

Item		Page
	PART I	
1.	Business	7
1A.	Risk Factors	22
1B.	Unresolved Staff Comments	55
1C.	Cybersecurity	55
2.	Properties	56
3.	Legal Proceedings	56
4.	Mine Safety Disclosures	57
	PART II	
5.	Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities	58
6.	[Reserved]	60
7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	61
7A.	Quantitative and Qualitative Disclosures About Market Risk	78
8.	Financial Statements and Supplementary Data	80
9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	135
9A.	Controls and Procedures	135
9B.	Other Information	135
9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	136
	PART III	
10.	Directors, Executive Officers, and Corporate Governance	136
11.	Executive Compensation	136
12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	136
13.	Certain Relationships and Related Transactions, and Director Independence	136
14.	Principal Accountant Fees and Services	136
	PART IV	
15.	Exhibits and Financial Statement Schedule	137
16.	Form 10-K Summary	142
	Signatures	143

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements include all statements that are not historical facts. Words such as "anticipate," "assume," "believe" "contemplate," "continue," "could," "estimate," "expect," "foreseeable," "intend," "may," "plan," "potentially," "predict," "project," "seek," "should," "will," or "would," or similar words or phrases that convey uncertainty of future events or outcomes, are intended to identify forward-looking statements in this Annual Report. These forward-looking statements relate to matters such as our industry, business strategy, costs, and costs savings, impacts of accounting standards and guidance, goals and expectations, market position, future operations, margins, profitability, capital expenditures, liquidity and capital resources, legal matters, trends, and other financial and operating information. The forward-looking statements are based on management's current expectations and are subject to various risks, uncertainty, and changes in circumstances, many of which are beyond our control, that could cause actual results to differ materially. Although we believe that the assumptions underlying the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance, or achievements. Factors that may cause actual results to differ from expected results include those described in Part I, "Item 1A—Risk Factors" and Part II, "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations". The forward-looking statements included in this Annual Report speak only as of the date of this Annual Report or as of the date they are made, as applicable. Except as otherwise required by law, we disclaim any intent or obligation to update any "forward-looking statement" made in this Annual Report to reflect changed assumptions, the occurrence of unanticipated events, or changes to future operating results over time.

INTRODUCTORY NOTE

Medline Inc. was incorporated as a Delaware corporation on November 6, 2024. Prior to the completion of its initial public offering (the "IPO") on December 18, 2025, Medline Inc. undertook certain reorganization transactions (the "Reorganization") such that Medline Inc. is now a holding company, and its sole material assets are its equity interests held directly or indirectly through wholly owned subsidiaries in Medline Holdings, LP ("Medline Holdings"). Following the IPO, Medline Holdings is the predecessor of Medline Inc. for financial reporting purposes. As the general partner of Medline Holdings, Medline Inc. now operates and controls all of the business and affairs of Medline Holdings and, through Medline Holdings and its subsidiaries, conducts its business. The Reorganization lacks economic substance and therefore is accounted for in a manner consistent with a reorganization of entities under common control. As a result, the consolidated financial statements of Medline Inc. recognize the assets and liabilities received in the Reorganization at their historical carrying amounts, as reflected in the historical financial statements of Medline Holdings. Medline Inc. will consolidate Medline Holdings on its consolidated financial statements and record a non-controlling interest related to the Units (as defined herein) held by the Continuing Unitholders (as defined herein) on its consolidated balance sheets and statements of comprehensive income.

Medline Inc. had no significant business transactions or activities prior to the Reorganization, and, as a result, the historical financial information reflects that of Medline Holdings.

Basis of Presentation

The consolidated financial statements and accompanying notes included herein are prepared in accordance with United States generally accepted accounting principles ("GAAP"). The results of businesses acquired or disposed of are included in the consolidated financial statements from the date of the acquisition or up to the date of disposal, respectively. All adjustments, in the opinion of management, necessary to a fair statement of the results for the annual periods presented have been made.

Certain monetary amounts, percentages, and other figures included in this Annual Report have been subject to rounding adjustments. Percentage amounts included in this Annual Report have been calculated, in some cases, not on the basis of such rounded figures, but on the basis of such amounts prior to rounding. For this reason, percentage amounts in this Annual Report may vary from those obtained by performing the same calculations using the figures, on the face of our consolidated financial statements included elsewhere in this Annual Report. Certain other amounts that appear in this Annual Report may not sum due to rounding.

In December 2024, we changed the name of Medline Holdings from Mozart Holdings, LP to Medline Holdings, LP. We will not distinguish between the prior and current name of Medline Holdings and will refer to the current name of Medline Holdings throughout this Annual Report. References in this Annual Report to "Medline," the "Company," "we," "us," and "our" refer (1) prior to the consummation of the IPO, to Medline Holdings, LP and its consolidated subsidiaries and (2) after the IPO to Medline Inc. and its consolidated subsidiaries.

CERTAIN DEFINITIONS

As used in this Annual Report, unless otherwise noted or the context requires otherwise, the following terms have the following meanings:

- "Class A Units" refers to the interests in Medline Holdings called "Class A Units" that were outstanding prior to the Reclassification. In connection with the Reclassification, (i) Class A Units held by Common Unitholders were converted into Common Units and (ii) Class A Units held by Exchanging Class A Unitholders were directly or indirectly exchanged for shares of Class A common stock.
- "Class B Units" refers to the interests in Medline Holdings called "Class B Units" that were outstanding prior to the Reclassification, and does not include CUPI Units. In connection with the Reclassification, (i) Class B Units held by Incentive Unitholders were converted into Incentive Units and (ii) Class B Units held by Exchanging Class B Unitholders were directly or indirectly exchanged for shares of Class A common stock (in the case of vested Class B Units) and/or restricted shares of Class A common stock (in the case of unvested Class B Units).

- "Common Units" refers to the new class of units of Medline Holdings created by the Reclassification and does not include Incentive Units.
- "Common Unitholders" refers to certain pre-IPO holders of Class A Units and/or CUPI Units who hold Common Units following the Reclassification.
- "Incentive Unitholders" refers to certain pre-IPO holders of Class B Units who will hold Incentive Units following the Reclassification, as described under "Organizational Structure."
- "Continuing Unitholders" refers collectively to Common Unitholders and Incentive Unitholders.
- "CUPI Units" refers to the interests in Medline Holdings that were designated as "Catch-Up Class B Units" and outstanding prior to the Reclassification. In connection with the Reclassification, (i) CUPI Units held by Common Unitholders were converted into Common Units and (ii) CUPI Units held by Exchanging CUPI Unitholders were directly or indirectly exchanged for shares of Class A common stock.
- "Designating Stockholder" refers to each of our Principal Stockholders with whom we entered into separate director nomination agreements.
- "Exchanging Class A Unitholder" refers to pre-IPO holders of Class A Units whose Class A Units were directly or indirectly exchanged for shares of Class A common stock following the Reclassification.
- "Exchanging Class B Unitholder" refers to pre-IPO holders of Class B Units whose Class B Units were directly or indirectly exchanged for shares of Class A common stock (in the case of vested Class B Units) and/or restricted shares of Class A common stock (in the case of unvested Class B Units) following the Reclassification.
- "Exchanging CUPI Unitholder" refers to pre-IPO holders of CUPI Units whose CUPI Units were directly or indirectly exchanged for shares of Class A common stock following the Reclassification.
- "Exchanging Unitholders" refers collectively to Exchanging Class A Unitholders, Exchanging CUPI Unitholders, and Exchanging Class B Unitholders.
- "Incentive Units" refers to the new class of units of Medline Holdings created by the reclassification of the Class B Units in the Reclassification. The Incentive Units are "profit interests" having economic characteristics similar to stock appreciation rights and having the right to share in any equity value of Medline Holdings above specified participation thresholds. Vested Incentive Units may be converted to Common Units and be subsequently exchanged for shares of Class A common stock.
- "Principal Stockholders" refers collectively to investment funds associated with Blackstone Inc., The Carlyle Group Inc. and Hellman & Friedman LLC, and members of the Mills family.
- "Reclassification" refers to the reclassification of the partnership interests of Medline Holdings prior to the IPO.
- "Sponsors" refers collectively to Blackstone Inc., The Carlyle Group Inc., and Hellman & Friedman LLC.
- "Units" refers collectively to Common Units and Incentive Units.

Summary of Risk Factors

The following is a summary of the principal factors that make an investment in our securities speculative or risky, all of which are more fully described below. This summary should be read together with the risk factors described under Part I, "Item 1A—Risk Factors" and should not be relied upon as an exhaustive summary of the material risks facing our business. In addition to the following summary, you should consider the information set forth below and the other information contained in this Annual Report before investing in our securities.

- Our global operations are subject to inherent risks that could materially adversely affect our business, results of operations, and financial condition.
- We may be unable to derive fully the anticipated benefits from our existing or future acquisitions, joint ventures, investments, dispositions, or other strategic transactions.
- Consolidation in the healthcare industry could have an adverse effect on our business, results of operations, and financial condition.
- We operate in a highly competitive industry, with accelerating pricing pressure and changes in technology.
- Changes to the U.S. and global healthcare environments may not be favorable to us.
- Increases in shipping costs or service issues with our third-party shippers could harm our business.

- Significant challenges or delays in our sourcing of new products and technologies could have an adverse impact on our long-term success.
- We have concentration in and dependence on certain healthcare provider customers and GPOs.
- Our business and operations depend on the proper functioning of our critical facilities and distribution networks and could be negatively impacted by events outside our control.
- Quality problems and product liability claims have in the past led, and could in the future lead, to recalls or safety alerts, reputational harm, adverse verdicts, or costly settlements, and could have a material adverse effect on our business, results of operations, and financial condition.
- Our failure to establish and maintain Prime Vendor relationships may cause our revenue to decline.
- If we experience increased pressure to maintain or decrease the price of our goods and services and we are unable to reduce our expenses, there may be a material adverse effect on our business, results of operations, and financial condition.
- Any failure by or loss of a third-party manufacturer or supplier or other manufacturing or supply-related impacts could result in delays and increased costs, which may adversely affect our business.
- We rely on the proper function, security, and availability of our information technology systems and data, as well as those of third parties throughout our global supply chain, to operate our business.
- We are subject to extensive and complex laws and governmental regulations and any adverse regulatory action may materially adversely affect our business, results of operations, and financial condition both inside and outside the United States.
- We are subject to complex and rapidly evolving data privacy, security, and data protection laws and regulations and the costs to comply with such laws and regulations or any ineffective compliance efforts with such laws and regulations may adversely impact our business.
- Our use or our third-party service providers' or business partners' use of AI, automated decision-making and machine learning technologies and the evolving regulatory framework in this area may subject us to risks or heightened costs that could adversely affect business, results of operation and financial condition.
- Our failure to comply with laws and regulations relating to reimbursement of healthcare goods and services may subject us to penalties and adversely impact our reputation, business, results of operations, financial condition, and cash flows.
- Uncertain global and domestic macro-economic and political conditions could materially adversely affect our business, results of operations, and financial condition.
- Our substantial indebtedness could adversely affect our financial condition, our ability to operate our business or react to changes in the economy or our industry, prevent us from fulfilling our obligations under our debts, and divert our cash flow from operations for debt payments.
- The credit agreement that governs the Senior Secured Credit Facilities and the indentures that govern the Senior Notes will each impose significant operating and financial restrictions on our subsidiaries, which may prevent us from capitalizing on business opportunities.
- Medline Inc. is a holding company and its only material assets are its equity interests held directly or indirectly through wholly owned subsidiaries in Medline Holdings, and it is accordingly dependent upon distributions from Medline Holdings to pay taxes, make payments under the tax receivable agreement, and pay any dividends.
- The Designating Stockholders hold a significant percentage of our stock, and their interests may conflict with ours or yours in the future.
- Our amended and restated certificate of incorporation does not limit the ability of our Sponsors, the Mills family, and certain other pre-IPO investors to compete with us, and they may have investments in businesses whose interests conflict with ours.

The market price of shares of our Class A common stock may be volatile or may decline regardless of our operating performance, which could cause the value of your investment to decline.

Market and Industry Data

Unless otherwise indicated, information contained in this Annual Report concerning our industry, competitive position, and the markets in which we operate is based on information from independent industry and research organizations, other third-party sources and management estimates. Although we believe that these third-party sources are reliable, we do not guarantee the accuracy or completeness of this information, and we have not independently verified this information. Management estimates are derived from information obtained from surveys, reports by market research firms, our customers, distributors, suppliers, trade and business organizations, and other contacts in the markets in which we operate and have not been verified by independent sources, and are based on assumptions made by us upon reviewing such data, and our experience in, and knowledge of, such industry and markets, which we believe to be reasonable. In addition, assumptions and estimates of our and our industry's future performance are subject to a high degree of uncertainty and risk due to a variety of factors, including those described in Part I, "Item 1A—Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

Statements regarding our market position (including statements that we are the largest company in a particular market), unless otherwise noted, are based on our 2025 net sales in the relevant market relative to the publicly reported net sales of our competitors in such market, including with respect to our statement of being the largest provider of med-surg products and supply chain solutions serving all points of care, as that statement is based on our 2025 net sales relative to the publicly reported net sales of med-surg products by companies that are both med-surg manufacturers and distributors.

Trademarks

We own or have the right to use trademarks, trade names, and service marks used in connection with our business, including, but not limited to, Medline, Curad, Microtek, Hudson, and Proxima. All trademarks, trade names, and service marks referred to in this Annual Report are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks, or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies. Solely for convenience, our trademarks, trade names, and service marks referred to in this Annual Report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names, and service marks.

PART I

Item 1. Business

General

Medline Inc. (together with its subsidiaries, "Medline", "the Company", "we", "ours" and "us") is the largest provider of medical-surgical ("med-surg") products and supply chain solutions serving all points of care, based on total net sales of med-surg products. Medline was founded in 1966 and today delivers mission-critical products used daily across the full range of care settings, from hospitals and surgery centers to physician offices and post-acute facilities. Our mission is to make healthcare run better by delivering improved clinical, financial, and operational outcomes.

We have two reportable segments, Medline Brand and Supply Chain Solutions, the combination of which addresses critical needs in the market through a comprehensive solution. They are both supported by our Prime Vendor model, differentiated distribution network, and robust commercial platform. Through our two segments, we offer approximately 335,000 med-surg products, including surgical and procedural kits, gloves and protective apparel, urological and incontinence care, wound care, and consumable lab and diagnostics products. We distribute these products through our expansive network of global distribution facilities and our owned fleet of MedTrans trucks.

Medline Brand

As of December 31, 2025, we offer our customers approximately 190,000 med-surg products through our Medline Brand segment and hold leading positions across many key product families for our Medline Brand products. Our Medline Brand products are organized into three product categories: Front Line Care, Surgical Solutions, and Laboratory and Diagnostics.

- *Front Line Care* offers mission-critical med-surg products for patient-facing needs, including wound care products, exam gloves, skin care and incontinence products, environment cleaning supplies, textiles, hand sanitizer, durable medical equipment, patient plastics, and decolonization and infection control products.
- *Surgical Solutions* offers operating room and perioperative environment product solutions, including surgical procedure trays, drapes and gowns, personal protective equipment, sterile wraps, surgical instruments, surgeon's gloves, procedure kits, and orthopedic implants.
- *Laboratory and Diagnostics* offers a full range of laboratory and diagnostic product solutions, including point of care testing, analyzers and instrumentation, lab and diagnostic consumables, diagnostic instruments, vital signs monitors, and anatomic pathology and phlebotomy products.

Our product development approach incorporates customer feedback and ongoing innovation. We are also committed to delivering products of the highest standard, which is reflected by our robust quality team embedded across our manufacturing and sourcing locations. The expertise of our research and development team and quality team helps ensure products bearing the Medline brand meet both our rigorous quality standards and our customers' expectations.

Supply Chain Solutions

As of December 31, 2025, we offer approximately 145,000 med-surg products from over 1,300 third-party suppliers, including nearly all leading national brands, through our Supply Chain Solutions segment. We also provide our customers with supply chain optimization services such as consulting engagements, outsourced warehouse and technology management, put-away-ready packaging, third-party logistics, inventory rationalization, and route planning. Our third-party suppliers are primarily responsible for costs related to import and inbound freight, whereas we are primarily responsible for costs related to outbound freight from our distribution centers. Our supply chain expertise allows us to provide additional service offerings to optimize our customers' supply chain and inventory workflows, helping these customers cost-effectively manage their supply chain while building strong relationships and enhancing retention.

Our Prime Vendor Model

A Prime Vendor relationship is a relationship for which there is a multi-year distribution agreement between Medline and a customer, whereby the customer agrees to use Medline for the vast majority of its med-surg product needs.

In our Prime Vendor relationships, we enter into long-term agreements, typically structured with five-year terms, to act as the primary consolidated logistics partner for these customers' med-surg product needs. These agreements have been and are expected to continue to be a key contributor to our growth. Our customers realize efficiencies by partnering with one supply chain partner to consolidate their med-surg purchase volume. Prior to the market adoption of the Prime Vendor model, customers sourced such products individually from a highly fragmented base of suppliers. The Prime Vendor model instead centralizes procurement and distribution, which in turn drives efficiency and higher service levels.

As Prime Vendor, we drive significant cost savings to our customers. Our scale allows us to deliver consistently lower prices and better service levels on Medline Brand products relative to third-party alternatives, while also lowering the distribution cost for delivery of the full range of med-surg products. This often motivates customers to purchase more Medline Brand products over time. The opportunity is even greater in certain non-acute settings, where we sell a more focused product portfolio. Our Prime Vendor model allows us to provide cost savings to Prime Vendor customers, which, over time, supports incremental purchasing of our Medline Brand products and greater scale across our operations. As our scale grows, we are able to realize further efficiencies by offering superior or similar quality to third-party products at a more cost-effective price. We believe that Medline Brand conversion is mutually beneficial for both our customers and us-the value we provide customers at the outset of a Prime Vendor agreement meaningfully increases over time, as they accrue savings by purchasing our lower cost Medline Brand products, while our profitability grows given the enhanced margin profile of Medline Brand products. This compelling value proposition and supply chain relationship with our customers supports our greater than 98% average Prime Vendor retention rate over the past five years.

A portion of Supply Chain Solutions products sold to existing Prime Vendor customers has like-for-like Medline Brand product equivalents, representing a potential gross profit uplift consistent with our historical margin differentials if such products were converted for Medline Brand products. While we historically have earned higher margins upon conversion from third-party national brand products to like-for-like Medline Brand products, because of the lower average prices for Medline Brand products, there is typically a negative impact on net sales upon the conversion of Supply Chain Solutions products to like-for-like Medline Brand products if volume is assumed to be constant. For additional information on potential risks relating to this conversion opportunity, please see Part I, "Item 1A—Risk Factors—Risks Related to Our Business, Industry and Operations—Our failure to establish and maintain Prime Vendor relationships may cause our revenue to decline."

Our Distribution Network

We have a differentiated distribution network of 70 global distribution centers, warehouses, cross-docks, and transship facilities, 45 of which are in the United States, strategically located to provide next-day delivery to 95% of our U.S. customer base. We utilize artificial intelligence ("AI") and robotics technology in over 26 million square feet of warehouse space in the United States to improve efficiency and capacity to optimize distribution logistics and maximize utilization. The products we distribute are packaged to meet each customer's individual needs and to be "put-away-ready," which streamlines the customer's unloading and shelving process. We also operate our own fleet of more than 2,100 MedTrans trucks that deliver our products across care settings within the United States. As of December 31, 2025, we had approximately 25% in incremental capacity across our platform to support our long-term growth.

Our Commercial Platform

Our deep connectivity to our customers is driven by the strength of our dedicated and tenured commercial team. We have a U.S. commercial team of approximately 4,000 people across all points of care, which includes account managers, product specialists, specialized clinical resources, customer service representatives, supply chain specialists, Prime Vendor analysts, and a robust leadership team dedicated to driving efficiencies for our customers through their teams. We have created an entrepreneurial environment that empowers our salesforce to work with our product managers to create innovative products that meet market demand. We have a team devoted to each channel in the United States and each region or country internationally, which allows our salesforce teams to develop market-specific knowledge.

Research and Development

We have a track record of successfully bringing new products to market, with more than 2,300 granted patents and more than 450 U.S. Food and Drug Administration ("FDA") 510(k) clearances. Over the last three years, we have successfully launched more than 250 new products.

Competition

Our value proposition is derived from our integrated business model, the breadth of our Medline Brand portfolio, our differentiated supply chain, and the overall quality and cost of our products. As a result of our integrated business model, our competitors include both other leading med-surg product manufacturers and distributors.

Similar to us, other leading med-surg product manufacturers produce a wide range of med-surg supplies. However, unlike us, many of these competitors are reliant upon third-party distributors to deliver their products to customers. By nature of being a distributor, Medline has direct access to and manages the end customer relationships. This enables us to offer a complete solution as a manufacturer and a distributor, offering our customers what we believe to be best-in-class supply chain logistics, and driving value through our brand.

Additionally, other distributors of med-surg products similarly connect the fragmented supplier and provider bases and aggregate inventory from suppliers to deliver products to customers, such as McKesson, Cardinal Health, Owens & Minor, and Henry Schein. These distribution companies compete with us for Prime Vendor agreements. However, we believe that many of these competitors do not benefit from the scale and scope of our vertical integration or commercial excellence, and thus are not able to provide the same magnitude of cost savings, value, and holistic solutions that we deliver for our customers.

Production and Raw Materials

We manufacture approximately one-third of our Medline Brand products, which are primarily Class I and II medical devices, through our 30 manufacturing facilities, of which 24 are in North America. We purchase many of the components and raw materials used in manufacturing our products from numerous suppliers. We focus our manufacturing capabilities on products where we can leverage technology and automation to drive higher quality and lower costs to better serve our customers. For the vast majority of the other two-thirds of our Medline Brand products, we work closely with our network of more than 600 global partners across approximately 40 countries, many of whom have decades-long exclusive relationships with us. The breadth of our global sourcing partnerships provides diversification and strengthens our resiliency, with no single sourcing partner accounting for more than 5% of total spend as of December 31, 2025.

We also have plans and measures in place to help ensure continuity of supply while maintaining high quality and reliability. Generally, we have been able to obtain adequate supplies of such raw materials and components. However, due to the FDA's manufacturing requirements and those of other regulatory authorities, we may not be able to quickly establish additional or replacement sources for certain components, materials or processes if we experience a sudden or unexpected reduction or interruption in supply or services and are unable to develop alternative sources.

Human Capital Resources

At Medline, our relentless focus on the customer drives our human capital strategy, which revolves around attracting, developing, and retaining employees to provide the best products and services for our customers. We have developed a strong foundation that drives our recruitment, retention and development efforts. We are committed to supporting the personal and professional development of our employees, as well as providing competitive benefits and a safe, inclusive workplace.

As of December 31, 2025, we employed over 45,000 employees worldwide, with over 26,000 located in the United States. Our largest non-U.S. employee populations are in Mexico, Dominican Republic, India, Canada, Slovakia, France, China, Japan, Germany, and Australia. None of our employees in the United States are unionized, though some of our employees in Mexico belong to unions. In Germany and the Netherlands, employees are represented through Works Councils; in France and Spain, employees are represented through both Works Councils and industry-wide collective bargaining agreements; and in Belgium and Italy, employees are also represented through industry-wide collective bargaining agreements. In Australia, certain employees are represented by an enterprise bargaining agreement; in Japan, employees are represented through a Work Council; and in Vietnam, employees are represented through a collective bargaining agreement. We believe that our positive employee relations and total employee experience drive the continual growth of our workforce.

Culture and Values

Our culture is grounded in a customer-focused, collaborative, and performance-driven approach, guided by core values emphasizing relentless customer focus, agility and flexibility, problem-solving, drive to succeed, purposeful candor, and the importance of relationships. Employees are encouraged to exercise judgment, work transparently with customers, and contribute meaningfully to our mission to make healthcare run better.

Talent Attraction and Development

We seek to attract employees whose skills, experience, and motivation align with our operational and technical needs. Through continual improvement of internal processes, an awareness of market and candidate driven trends, and in partnership with vendors and other outside organizations, our talent acquisition programs focus on efficient hiring processes, market awareness, and building a diverse pipeline of candidates. We support development through consistent performance management processes and early career opportunities to take on additional responsibilities to demonstrate their competencies and drive to succeed and on-the-job responsibility augmented by formal training and development to refine technical and leadership skills. New sales representatives participate in comprehensive training programs, and product managers have targeted development pathways through all stages of their careers, from mandatory onboarding offerings to advanced classes that provide the necessary skills with increasing levels of responsibility, to support progression over time.

Employee Engagement and Inclusion

We believe our employees' ability to communicate and cooperate effectively across functional and departmental teams positively impacts our performance. We engage in various listening strategies and foster engagement through survey feedback mechanisms, anonymous employee feedback platform, focus groups, increased attention to onboarding and offboarding feedback, pulse surveys on remote work needs, and other listening strategies. Insights from these efforts inform workplace improvements. We also support an inclusive environment through Employee Resource Groups and leadership training initiatives designed to reduce bias in talent decisions and strengthen representation across the company.

Health, Safety, and Well-Being

We are committed to maintaining a safe workplace and supporting the physical, emotional, and financial well-being of our employees. We provide competitive health and benefits programs, access to assistance resources where available, and opportunities for community involvement through charitable giving, including financial giving and in-kind giving such as product donations.

Intellectual Property

We rely upon patents, trademarks, copyrights, trade secrets and other intellectual property rights to maintain and improve our competitive position. We have a large portfolio of intellectual property, including more than 2,300 granted patents as well as trademark registrations protecting our notable brands, including Medline, Curad, Microtek, Hudson, and Proxima.

We consider the trademarks and know-how that we own to be material to our business. However, other than the Medline mark, we do not consider our business to be materially dependent upon any individual trademark registration or trade secret. In the aggregate, we consider our more than 2,300 granted patents to be material to our business. However, no single patent or group of related patents is material to our business as a whole or any segment of our business.

We believe that we have taken all necessary steps to protect our intellectual property rights, but no assurance can be given that we will be able to successfully enforce or protect our rights in the event that they are infringed upon or challenged by a third party. See Part I, "Item 1A —Risk Factors—Risks Related to Regulation and Legal Proceedings—Any failure to obtain, maintain, protect and enforce our intellectual property rights, or the failure of the strength or scope of our intellectual property rights, could harm our business, financial condition, and results of operations" and "—Risks Related to Regulation and Legal Proceedings—We may become subject to litigation brought by third parties claiming infringement, misappropriation, or other violation by us of their intellectual property rights."

Government Regulation

Our operations and products are subject to extensive regulation by numerous governmental regulatory authorities, including U.S. and other international regulatory authorities, and other government agencies inside and outside the United States. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, design, materials, testing, safety, efficacy, quality, purity, manufacturing, methods, controls, testing, screening, recordkeeping, reporting, processing, storage, registration, authorization, licensing, permitting, labeling, advertising, marketing, distribution, offer for sale, sale, use, expiration, pricing, reimbursement, import, export, clinical trials, post-marketing surveillance of our products, the registration of our facilities, and the claims that we make about our products. The United States and other countries where we sell healthcare and other regulated products, including drugs, human cell and tissue products, dietary supplements, cosmetics, certain foods, and consumer products subject such products to their own clearance, authorization, approval, registration, listing, labeling, manufacturing, recordkeeping, reporting, and other regulatory requirements regarding the performance, safety, and quality of such products. We are also subject to healthcare and other regulations and enforcement by the federal government and the states and foreign governments and authorities in the locations in which we conduct our business. The U.S. governmental and regulatory authorities that enforce such laws and rules, and that issue guidance on compliance with such laws and rules include, without limitation, the FDA, the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the U.S. Department of Health and Human Services ("HHS"), the HHS Office of Inspector General, U.S. Environmental Protection Agency ("EPA"), the Federal Trade Commission ("the FTC"), Consumer Product Safety Commission ("CPSC"), the U.S. Department of Justice ("DOJ") and individual U.S. Attorney offices within the DOJ, as well as state and local governments. Our business is also affected by patient and data privacy and security laws, government payer cost containment initiatives, government reimbursement laws and regulations, environmental, health, and safety laws and regulations, as well as laws and regulations with respect to the sale, transportation, storage, handling, and disposal of hazardous or potentially hazardous substances, and safe working conditions. Our business also maintains contracts with governmental agencies and such contracts are subject to various government procurement laws and regulations, required contract provisions, and other requirements relating to contract formation, administration and performance. Failure to comply with applicable laws and regulations or with contractual or other requirements may result in monetary damages and criminal or civil penalties as well as termination of our government contracts or our suspension or debarment from government contract work.

The regulations to which we are subject are complex and have tended to become more stringent over time. If our business expands in certain ways, including through the offering of new products and services or entering into new geographic areas, we may be subject to new and additional regulatory requirements. The foreign, federal, state, and local regulatory authorities have broad inspection and enforcement powers, including the ability to suspend or limit the distribution of products, suspend, revoke, or terminate our product and facility licenses, permits, and authorizations, request the cessation of distribution and shipments of certain products due to regulatory, safety, or other issues, seize or order the recall of our products, issue safety, quality, or other communications to the public or healthcare providers, enforce laws related to marketing, including promotion of off-label uses of products, and impose injunctions and significant criminal, civil, and administrative sanctions for violations of laws and regulations. Any adverse regulatory or other action, including any adverse press releases or other communications from regulators, may impact our business practices and operations, including by limiting our ability to effectively market, ship, and sell our products, affecting the production and distribution of products by our manufacturing facilities, subjecting us to significant liability, and limiting our ability to obtain future authorizations. Although we are subject to international government regulations in the international end markets where we operate and/or provide our products, these regulations do not have a material impact on our products as no international market represents more than 3% of our net sales.

Government Regulation of Medical Devices

Our medical devices are subject to regulation by numerous government agencies, including the FDA and comparable state and foreign agencies. Regulations of the FDA and other regulatory agencies in and outside the United States impose extensive compliance and monitoring obligations on portions of our business. The FDA and other U.S. and foreign governmental agencies regulate, among other things, with respect to medical devices: design, development, and manufacturing; testing, registration, listing, labeling, content, and language of instructions for use and storage; clinical trials; product safety; marketing, sales, and distribution; licensing and permit requirements; premarket clearance, approval and authorization; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval studies; and product import and export. The regulations to which we are subject are complex and have tended to become more stringent over time. If our business expands in certain ways, we may be subject to new and additional regulatory requirements. The FDA and state regulatory authorities have broad inspection and enforcement powers, including the ability to suspend or limit the distribution of products by our distribution centers; seize or order the recall of products; terminate, suspend, or revoke licenses and permits; and impose significant criminal, civil, and administrative sanctions for violations of these laws and regulations. Foreign regulations subject us to similar foreign enforcement powers. In addition, the FDA and other governmental and regulatory authorities, both in and outside the United States (including the FTC, the HHS Office of the Inspector General, the DOJ, and various state Attorneys General), monitor the promotion and advertising of our products. Any adverse regulatory or other action, including any adverse press releases or other communications from regulators, depending on its magnitude, may limit our ability to effectively market, ship, and sell our products, limit our ability to obtain future premarket authorizations, or result in a substantial modification to our business practices and operations.

FDA Premarket Clearance and Approval Requirements

Each medical device we wish to distribute commercially in the United States requires marketing authorization from the FDA prior to distribution, unless the device is exempt from premarket notification requirements. The type of marketing authorization necessary is generally linked to the classification of the device. The FDA classifies medical devices into one of three classes-Class I, II, or III-based on the degree of risk associated with a device and the level of regulatory control deemed necessary to ensure its safety and effectiveness. Class I devices that pose the least risk are subject only to General Controls applicable to all devices, such as requirements for device labeling, premarket notification, and adherence to current good manufacturing practices for devices as set forth in the Quality System Regulation ("QSR"). Class II devices that pose a moderate risk are subject to General Controls and may also be subject to Special Controls, such as performance standards, product-specific guidance documents, special labeling requirements, patient registries, or post-market surveillance. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through General and Special Controls, including devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential unreasonable risk of illness or injury.

Most Class I devices and some Class II devices are exempted by regulation from the 510(k) clearance requirement and can be marketed without prior authorization from the FDA. Class I and II devices that are not exempted are eligible for marketing through the 510(k) clearance pathway. By contrast, devices placed in Class III generally require premarket approval ("PMA") or de novo clearance prior to commercial marketing. The PMA approval process is more stringent, time-consuming and expensive than the 510(k) clearance process; however, the 510(k) clearance process has also become increasingly stringent and expensive. None of our products are currently approved under a PMA, and we have no plans for any indication or system improvement or extension that we believe would require a PMA. If, in the future, we were to file a PMA, we may be subject to additional regulatory requirements.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

*See Attachment 1 - Corporate Disciplinary History

previously serviced
3. Approved

Original Signature (electronic, copies or stamps not accepted)

08/10/20
Date

Attachment 1

Medline Industries, LP- Discipline *Confidential*

Date of Resolution	Facility	Description
08/03/2005	1401 N. Universal Ave Kansas City, MO 64120	**Case:** 2003031660 **Agency:** Missouri Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement, 5 years' probation **Summary:** Medline Industries Inc. distribution center at 1401 N. Universal Ave, Kansas City, MO 64120 (MO# DD2003031660) cited for failure to renew on time and deficient temperature control procedures. All issues resolved via Settlement Agreement effective 08/03/2005. License placed on probation for 5 years. The state conducted multiple inspections of the facility throughout the probationary period and found Medline to comply with all requirements. The probationary period closed in August 2010. **Corrective Actions:** Medline hired additional staff to monitor and ensure on-time license renewal. A temperature control room was constructed at the facility to ensure products are stored at the appropriate temperature and humidity.
12/07/2006	9101 Riverside Pkwy Lithia Springs, GA 30122	**Case:** N/A **Agency:** Florida Department of Health **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Temporary Suspension Lifted **Summary:** Medline Industries Inc. distribution center at 9101 Riverside Pkwy Lithia Springs, GA 30122 Non-Resident FL Permit (FL # 23:1470) suspended for operating without a FL Certified Designated Representative. The CDR resigned unexpectedly. Upon receipt of the notice of intent to suspend, Medline stopped all shipments into the state of FL. Permit was reinstated upon hiring of a new licensed Florida CDR. **Corrective Actions:** Qualified FL Certified Designated Representative hired for facility. Medline implemented a policy requiring all FL licensed distribution centers to maintain a backup Florida Certified Designated Representative on staff.
02/08/2008	2708 NE Waldo Rd. Gainesville, FL 32609	**Case:** 2007-37412 **Agency:** Florida Department of Health **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement **Summary:** Medline Industries, Inc. distribution center at 2708 NE Waldo Rd., Gainesville, FL 32609 FL Permit (FL # 22:1022) suspended for violations identified during a Florida BOP facility inspection. Medline, through Counsel, addressed the issues raised in the inspection and established that the suspension was unjustified. The suspension was lifted 3 days later on January 22, 2008. Medline Industries, Inc. entered into a settlement agreement on 02/08/2008 with the FL Department of Health to resolve all issues related to the case. **Corrective Actions:** Medline conducted a thorough review of its policies and procedures and implemented an internal auditing program to ensure that all distribution centers comply with internal policies and procedures and state and federal regulations.
05/01/2008	149 New Camellia Blvd. Covington, LA 70433	**Case:** 2008006 **Agency:** Louisiana Board of Wholesale Drug Distributors **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Consent Decree **Summary:** Medline Industries Inc. distribution center at 149 New Camellia Blvd. Covington, LA 70433 (LA #4318) cited for failure to properly maintain copies of current customer licenses on-site. Licenses were maintained by Medline's Regulatory team at corporate headquarters. Medline entered a consent decree effective 05/01/2008 to resolve the alleged violation. **Corrective Actions:** Medline implemented digital storage of customer licenses to allow for on-demand access by distribution centers.

Medline Industries, LP- Discipline *Confidential*

07/08/2008	94-1420 Moaniani St. Waipahu, HI 96797	**Case #:** PHA 2008-71-L **Agency:** Hawaii Department of Commerce and Consumer Affairs **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, Inc. distribution center at 94-1420 Moaniani St., Waipahu, HI 96797 (HI # PWD 115) entered a settlement agreement and placed on probation for 5 years for failure to report disciplinary actions within 30 days. Medline submitted all required notices but missed the 30-day deadline. The probationary period ended in August 2013. **Corrective Actions:** Medline implemented a policy and procedure to notify licensing boards of disciplinary actions within the required reporting timelines.
09/06/2008	10601 Southport Dr. Orlando, FL 32824 _____ 401 Commerce Blvd. Oldsmar, FL 34677 _____ 4750 118th Ave N Clearwater, FL 33762	**Case #:** 2007-11783; 2007-36555; 2007-38894; 2007-38895; 2007-38896; 2007-39073; 2008-02011; 2008-11215 **Agency:** Florida Department of Health **Entity:** Medline Industries, Inc.; Medline Manufacturing & Services, LLC **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries Inc. and Medline Manufacturing & Services, LLC was cited for several violations related to distribution centers in Florida, including, failure to pass and maintain a Florida compliant pedigree, maintaining the wrong permit type for the activities performed (Florida required a repackager permit in addition to the existing manufacturer permit), distribution of saline to an unauthorized recipient, and storage of a prescription drug in an unlicensed raw materials storage facility. Medline challenged several violations, resulting in most being substantially reduced or removed. All issues were addressed and resolved to the satisfaction of the FL DOH. A settlement agreement was reached to resolve all matters and approved on 09/06/2008. **Corrective Actions** Medline instituted a Florida specific pedigree system to address the pedigree issues. The updated pedigree ensures that all applicable shipments to Florida have the required Florida documentation and comply with FL pedigree requirements (Note - these requirements have since been preempted by the federal Drug Supply Chain Security Act). Medline secured the repackaging permit to address the missing permit type. Medline instituted a new procedure for obtaining and maintaining customer licenses for all prescription drug purchases- this procedure generates an automatic block for any prescription drug order by an unlicensed customer. The prescription drug item unintentionally stored in the raw materials facility was properly disposed of and waste disposal procedures updated to prevent this from occurring in the future.
02/04/2009	5450 W. Stewart Ave. Wausau, WI 54401	**Case:** 08 PHM 037 **Agency:** Wisconsin Department of Regulation and Licensing **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Stipulation Order **Summary:** Medline Industries Inc. distribution center at 5450 W. Stewart Ave., Wausau, WI 54401 (WI # 1116-045) cited for missing policies and procedures and storage of drugs in a non-secure location following an inspection by the Wisconsin Department of Regulation & Licensing. Medline managed a portion of a Wisconsin hospital's warehouse. The inspector cited Medline for failure to install a dividing fence between the Medline warehouse and the hospital portion of the facility. All hospital products were owned by the hospital. Medline was also cited for failure to access policies and procedures during the inspection. Corrections were made and the facility re-inspected, to the satisfaction of the state. Medline entered a stipulation order effective 02/04/2009 to resolve the matter. **Corrective Actions:** Medline installed a locked fence to separate the hospital's owned products. Medline also completed a review of all facilities to ensure proper separation of products. On-site staff provided additional training on how to access current policies and procedures during an inspection.

Medline Industries, LP- Discipline *Confidential*

05/19/2009	94-1420 Moaniani St. Waipahu, HI 96797	**Case:** PHA 2009-7-L **Agency:** Hawaii Department of Commerce and Consumer Affairs **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, Inc. agreed to enter a Consent Order for discipline incurred in another jurisdiction (Wisconsin Case #: 08 PHM 037). **Corrective Actions:** See Corrective Actions for Case #: 08 PHM 037.
03/19/2010	1401 N. Universal Ave. Kansas City, MO 64120	**Case:** 2010-002994 **Agency:** Colorado State Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Stipulation **Summary:** Medline Industries, Inc. distribution center at 1401 N. Universal Ave, Kansas City, MO 64120 applied for a Colorado Out-of-State Wholesaler license. The CO Board of Pharmacy issued a conditional license until the facility's MO probation period ended. (See Case 2003031660 above). Medline informed the CO Board when the MO probationary period was completed. Upon completion of probation, the Board issued a full license. **Corrective Actions:** Medline successfully completed terms of probation in MO and CO.
07/18/2014	3301 Route 6 Middletown, NY 10940	**Case:** 27278 **Agency:** NY State Education Department- Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Consent Order **Summary:** Medline Industries, Inc. agreed to enter a Consent Order for discipline incurred in another jurisdiction (FL No. 2007-37412, LA No. 2008006, and WI No. 08 PHM 037). **Corrective Actions:** See corrective actions for FL No. 2007-37412, LA No. 2008006, and WI No. 08 PHM 037.
01/06/2021	1501 Harris Rd Libertyville, IL 60048	**Case:** A-2020-0054 **Agency:** Ohio Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, Inc. distribution center at 1501 Harris Rd Libertyville, IL 60048 (OH License #01-1985050) entered into a settlement agreement with the Ohio Board of Pharmacy for the sale of dangerous drugs to an unlicensed entity. Medline maintained a current and valid DEA license on file rather than the correct Terminal Distributor Dangerous Drugs license (TDDD). The facility's TDDD license expired at the time of the sale. Case resolved via Settlement Agreement effective 01/06/2021. **Corrective Actions:** Medline updated its customer license requirements for Ohio customers. Medline completed a review of all Ohio customers to verify the correct license type was on file and implemented increased verification checks of Ohio licenses.

Medline Industries, LP- Discipline *Confidential*

06/28/2021	1501 Harris Rd Libertyville, IL 60048	**Case:** 21-L-0048 **Agency:** Alabama Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Order **Summary:** Medline Industries, Inc. distribution center at 1501 Harris Rd Libertyville, IL 60048 (AL Non-Resident Permit #193718) was fined for discipline incurred in another jurisdiction (OH A-2020-0054) **Corrective Actions:** See corrective action for OH A-2020-0054.
11/01/2022	1040 Enterprise Parkway South West Jefferson, OH 43162	**Case:** A-2022-0333 **Agency:** Ohio Board of Pharmacy **Entity:** Medline Industries, LP **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, LP distribution center at 1040 Enterprise Parkway South, West Jefferson, OH 43162 (OH License #01-30000190) entered a settlement agreement with the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file instead of the correct Terminal Distributor Dangerous Drugs license (TDDD). The TDDD license was added in May 2022. During the period of July 2021 to March 2022, the customer's TDDD license lapsed, and Medline shipped the customer product under the valid practitioner license. Case resolved via Settlement Agreement effective 11/01/2022. **Corrective Actions:** Medline updated customer licensing requirements for Ohio customers following OH Case # A-2020-0054. The shipments in this matter occurred while Medline was in the process of reviewing and updating all Ohio customer licenses. Medline licensing staff were also provided with additional training on Ohio license requirements.
12/19/2022	9670 NW 112th Ave Miami, FL 33178	**Case:** 2022-031132 **Agency:** FL Dept. Business and Professional Regulation, Div. of Drugs, Devices, and Cosmetics **Entity:** Medline Industries, LP **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, LP distribution center at 9670 NW 112th Ave, Miami, FL 33178 (FL WDD# #2220297) entered a settlement agreement for alleged violations of selling prescription drugs to an unauthorized recipient and failure to maintain proper records. Medline accepted a physician license for a customer which should have maintained a Healthcare Clinic Establishment Permit. The recordkeeping allegation related to missing NDC numbers on outbound packing slips and invoices. **Corrective Actions:** Medline updated customer licensing requirements for Florida customers and completed an extensive review of all FL customer licenses to verify the correct license type was on file. Medline determined the missing NDC number on the packing slip and invoice occurred due to an internal system error. The error was limited to DSCSA exempt products, i.e. IV fluids. A fix was implemented to correct the issue.

Medline Industries, LP- Discipline *Confidential*

07/19/2023 07/25/2023	1040 Enterprise Parkway South West Jefferson, OH 43162 251 Hilton Drive Jeffersonville, IN 47130	Case: A-2022-0307, A-2022-0184 **Agency:** Ohio Board of Pharmacy **Entity:** Medline Industries, LP **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, LP distribution centers at 1040 Enterprise Parkway South, West Jefferson, OH 43162 (OH License #01-30000190) and 251 Hilton Drive. Jeffersonville, IN 47130 (OH License #01-30000158) entered settlement agreements with the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. The sales occurred between July 2021 and January 2022. Medline maintained valid practitioner licenses on file for each customer instead of the correct d sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file instead of the correct Terminal Distributor Dangerous Drugs license (TDDD). Cases resolved via Settlement Agreement effective 07/19/2023 and 07/25/2023. **Corrective Actions:** Medline updated customer licensing requirements for Ohio customers following OH Case # A-2020-0054. The shipments in this matter occurred between July 2021 and January 2022 while Medline was in the process of reviewing and updating all Ohio customer licenses.
12/21/2023	2341 Lauwiliwili St. Kapolei, HI 96707	**Case:** PHA 2023-9-L **Agency:** Hawaii Department of Commerce and Consumer Affairs **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, LP distribution center at 2341 Lauwiliwili St, Kapolei, HI 96707 (HI #) entered a Settlement Agreement for discipline incurred in another jurisdiction (OH A-2022-0333, OH A-2022-0307, OH A-2022-0184, and FL 2022-031132) **Corrective Actions:** See corrective actions for OH A-2022-0333, OH A-2022-0307, OH A-2022-0184, and FL 2022-031132.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	08/03/2005	MO	Kansas City	Jackson

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2003031660	Missouri Board of Pharmacy

Reason/Charge
Failure to Renew on Time; Temperature Control Deficiency

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
MO Board of Pharmacy/ Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries Inc. distribution center at 1401 N. Universal Ave, Kansas City, MO 64120 (MO# DD2003031660) cited for failure to renew on time and deficient temperature control procedures. All issues resolved via Settlement Agreement effective 08/03/2005. License placed on probation for 5 years. The state conducted multiple inspections of the facility throughout the probationary period and found Medline to comply with all requirements. The probationary period closed in August 2010.

Corrective Actions:
Medline hired additional staff to monitor and ensure on-time license renewal. A temperature control room was constructed at the facility to ensure products are stored at the appropriate temperature and humidity.

Original Signature (electronic, copies or stamps not accepted)

07/30/20
Date

Jeremiah W. (Jay) Nixon
Governor
State of Missouri

Jane A. Rackers, Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance
Financial Institutions
and Professional Registration
John M. Huff, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573-751-0091 PHONE
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kimberly A. Grinston
Executive Director
www.pr.mo.gov/pharmacists.asp
e-mail: pharmacy@pr.mo.gov

08/03/2010

Charlie Mills
One Medline Place
Mundelein, IL 60060-4486

Dear Mr. Mills,

This is official notification that you have completed your terms of Probation with the Missouri Board of Pharmacy as of August 2, 2010.

If you have any questions, or if we can be of assistance in the future, feel free to contact this office. Thank you for complying.

Sincerely,

Jason Menken
Compliance Coordinator
Missouri Board of Pharmacy

Matt Blunt, Governor
State of Missouri

Alison Craighead, Director
Division of Professional Registration

Gregory A. Steinhoff, Director
Department of Economic Development

BOARD OF PHARMACY
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573-751-0091
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kevin E. Kinkade, R.Ph.
Executive Director

www.pr.mo.gov/pharmacists.asp
e-mail: pharmacy@pr.mo.gov

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
7160 3901 9848 6160 3154

August 4, 2005

Mr. Pete Furlong, Corporate Vice President
Quality Assurance/Regulatory Affairs
Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060-4486

Dear Mr. Furlong:

Enclosed is an executed copy of the **Settlement Agreement Between State Board of Pharmacy and Medline Industries, Inc.** A permanent drug distributor license, numbered 2003031660, has been issued to Medline Industries, Inc., 1401 N Universal Avenue, Kansas City, MO, and is being mailed to the facility with a copy of this letter. That license has been placed on probation August 3, 2005, through August 2, 2010.

A 2005-2007 Drug Distributor Renewal Application will be mailed to the facility within the next two weeks. This form must be completed and returned with the $400.00 fee before October 31, 2005.

You should review each term of this Agreement and comply with the requirements as set forth. Compliance is your responsibility; reminders will not be sent from this office. Licensee Report of Discipline Compliance forms are being included with the mailing to the facility and should be completed and submitted to the Board office within six months from the beginning of the probation period and every six months following that for the duration of the probation. Failure to comply with the terms of this Agreement may result in a violation hearing before the Board.

If you have any questions, please feel free to contact this office at 573-751-9056.

Sincerely,

DON WALKER
Drug Distributor Coordinator

Enclosures
cc: Rob Angstead, Attorney
Scott C Barbour, Manager-in-Charge

SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND MEDLINE INDUSTRIES, INC.

Come now Medline Industries, Inc. ("Respondent") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's license as a drug distributor will be subject to discipline.

Pursuant to the terms of § 536.060, RSMo (2000), the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under § 621.110, RSMo (2000), and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its license. Being aware of these rights provided it by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document, as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the Board, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's license. For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this

Settlement Agreement are true and stipulates with the Board that Respondent's temporary license as a drug distributor, License Number DD2003031660, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo 2000. The parties agree that this Settlement Agreement and any statements contained herein may not be used for or constitute an admission for any purposes other than to settle the disputes between the parties.

Joint Stipulation of Facts

1. Petitioner, the Missouri Board of Pharmacy ("the Board"), is an agency of the State of Missouri created and established by § 338.110, RSMo (2000), for the purpose of administering and enforcing the provisions of Chapter 338, RSMo.

2. Respondent, Medline Industries, Inc., located at 4700 Deramus, Kansas City, Missouri, is licensed by the Board as a drug distributor under the laws of Missouri, License Number DD2003031660. The license is current and active.

3. On or about April 16, 1996, Wilson Winch, an inspector for the Board, conducted an inspection at the facility located at 1691 N. Topping, Kansas City, Missouri.

4. Inspector Winch noted on the Drug Distributor Inspection Observation Report that Respondent needed temperature/humidity recording equipment and that the results must be logged daily.

5. On or about August 8, 1997, Tom Glenski, an inspector for the Board, conducted an inspection at the facility located at 1250 N. Southern, Kansas City, Missouri.

6. Inspector Glenski noted on the Drug Distributor Inspection Observation Report that Respondent needed a temperature and humidity daily log.

7. On or about September 3, 1997, the Board received a written response dated August 27, 1997, from Lara Simmons, Respondent's Director of Regulatory Affairs, explaining that a temperature and humidity monitoring device was being purchased and the temperature and humidity will be recorded daily during days of operation.

8. Ms. Simmons indicated that she anticipated the temperature and humidity monitoring device would be in place and the recordkeeping started by the first of September, 1997.

9. On or about July 31, 1998, Inspector Tom Glenski conducted an inspection at the facility located at 1250 N. Southern, Kansas City, Missouri.

10. Inspector Glenski noted on the Drug Distributor Inspection Observation Report that Respondent needed to keep daily temperature and humidity recordings.

11. Respondent failed to purchase the temperature and humidity monitoring device as Ms. Simmons indicated would be purchased.

12. Respondent's failure to provide an appropriate temperature and humidity monitoring device is in violation of 21 CFR § 211.46(b) which states:

> (b) Equipment for adequate control over air pressure, micro-organisms, dust, humidity, and temperature shall be provided when appropriate for the manufacture, processing, packing, or holding of a drug product.

13. On September 9, 1998, the Board sent a Compliance Letter to Respondent for a number of non-compliance issues found on the July 31, 1998 inspection, one of which was "temperature/humidity daily log documentation".

14. On or about September 2, 1999, Inspector Glenski conducted an inspection at the facility located at 1250 N. Southern, Kansas City, Missouri.

15. Inspector Glenski noted on the Drug Distributor Inspection Observation Report that the warehouse temperature exceeded the manufacturer's recommended storage temperature of 86 degrees Fahrenheit.

16. On or about October 4, 2000, Inspector Glenski conducted an inspection at the facility located at 1250 N. Southern, Kansas City, Missouri.

17. Inspector Glenski noted on the Drug Distributor Inspection Observation Report that the temperature exceeded 86 degrees on various days between July, 2000 and September, 2000.

18. On or about September 20, 2001, Frank Van Fleet, an inspector for the Board, conducted a change-of-location inspection at the facility located at 4700 Deramus, Kansas City, Missouri.

19. Inspector Van Fleet noted on the Observation Report that the temperature exceeds 86 degrees on not less than 32 occasions between June 8, 2001 and September 5, 2001.

20. On or about May 21, 2003, Inspector Van Fleet conducted an inspection at the facility located at 4700 Deramus, Kansas City, Missouri.

21. Inspector Van Fleet noted on the Observation Report that the temperature exceeded 86 degrees on not less than 41 occasions between June 3, 2002 and September 30, 2002.

22. On or about August 19, 2003, Inspector Van Fleet conducted a follow-up inspection at the facility located at 4700 Deramus, Kansas City, Missouri.

23. Inspector Van Fleet monitored storage temperatures with a digital thermometer at various locations where prescription product was stored.

24. Three additional occasions were identified between September 30, 2002 and August 19, 2003 where the temperature exceeded 86 degrees.

25. Inspector Van Fleet found that storage temperatures were much higher than the temperatures Respondent had recorded on its log.

26. Inspector Van Fleet's digital thermometer registered a range from 89.1 degrees in one area where Respondent stored bulk prescription hydrating/electrolyte solutions to as high as 94.5 degrees in Respondent's over the counter storage area, but Respondent's temperature log records a temperature of 89 degrees for this date.

27. Inspector Van Fleet presented at the 4700 Deramus facility on March 2, 2004 for tbe purpose of conducting a new facility inspection.

28. Inspector Van Fleet found 16 occasions between October 31, 2003 and February 27, 2004 where the temperature in the warehouse dropped below 59 degrees.

29. Respondent's warehouse is divided into three areas by breezeways.

30. Respondent has only one digital monitor for 120,000 square feet of warehouse.

31. The warehouse is not air-conditioned, and even though it is heated, logs show product was stored at less than 59 degrees.

32. Respondent has a history of noncompliance regarding the storage of prescription product.

33. Monitoring temperature and/or storing product at manufacturer's recommended/required humidity and storage temperature has been an issue on every inspection since 1996 involving three different locations and three different inspectors.

34. Respondent has been in at least three different warehouses in the last six years and

has failed each time to choose a warehouse that is temperature controlled.

35. Drugs must be stored in accordance with manufacturer or USP guidelines and must be free of contamination, deterioration and adulteration.

36. Drugs stored outside of manufacturer or USP guidelines can become contaminated, deteriorated and adulterated.

37. A drug shall be deemed adulterated pursuant to 21 USC 351(a)(2)(B) which states:

> A drug or device shall be deemed to be adulterated –
>
> > (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to the safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess . . .

38. Respondent's failure to maintain a facility where temperature is controlled and humidity is maintained is in violation of 4 CSR 220-5.030(3)(B) which states in pertinent parts:

> (3) Minimum standards of practice for drug distributors shall include the following:
>
> > (B) The temperature of the facility where drugs are stored must be maintained within temperature requirements as provided for by the manufacturer or the latest edition of the *United States Pharmacopeia* (USP). Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, logs, or all of these, shall be utilized to document proper storage of prescription drugs.

> (C) Appropriate housekeeping, sanitation, lighting, ventilation and humidity of all areas where drugs are stored must be maintained.

39. On or about April 16, 1997, Inspector Winch attempted an inspection at the facility located at 1691 N. Topping, Kansas City, Missouri and observed that Respondent had changed locations without notifying the Board.

40. Respondent's failure to timely notify the Board of its change of location and continue its operation as a wholesale drug distributor is in violation of 4 CSR 220-5.020(6) which states:

> (6) If an individual or business entity operating a drug distributor facility changes the location of the facility either within the existing facility (structure) or to a new facility (structure), the facility shall not open for business at the new location until the board, its duly authorized agent or the Food and Drug Administration has inspected the premises of the new location and approved it and the facility has been in compliance with all state and federal drug laws pertaining to drug distribution. Upon the approval and receipt of a change of location fee, the board shall issue a permit authorizing operation of a facility at the new location and the permit shall bear the same number as the previous license. However, the license remains valid if the facility address changes, but not the location, and an amended license will be issued without charge under these circumstances.

41. On or about August 8, 1997, Inspector Glenski conducted an inspection at the facility.

42. The inspector noted on the Drug Distributor Inspection Observation Report that Respondent needed a complete policy and procedure manual.

43. On or about September 2, 1999, Inspector Glenski conducted an inspection at the facility located at 1250 N. Southern, Kansas City, Missouri.

44. Inspector Glenski noted on the Drug Distributor Inspection Observation Report

that Respondent's policy and procedure manual could not be located.

45. Respondent's failure to establish and maintain a completed policy and procedure manual is in violation of 4 CSR 220-5.030(3)(M) which states in pertinent parts:

> (3) Minimum standards of practice for drug distributors shall include the following:
>
> > (M) Wholesale drug and pharmacy distributors shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts and for correcting all errors and inaccuracies in inventories.

46. On October 31, 2003, Respondent's drug distributor license expired.

47. Respondent failed to renew its license by the renewal deadline of November 30, 2003.

48. Respondent's license became null and void on November 30, 2003.

49. The Board received a new application from Respondent on or about December 16, 2003.

50. The Board issued Respondent temporary license number 2003031660 on December 29, 2003.

51. From the time Respondent's license became null and void on November 30, 2003, until the Board's issuance of Respondent's temporary license on December 29, 2003, Respondent failed to display a valid license.

52. Respondent's failure to display a valid license is in violation of 4 CSR 220-5.020(8)(B) which states:

> (B) A license must be posted in a conspicuous place in the

facility to which it is issued.

53. Respondent's invoice number 1016623706 shows the distribution of several Irrigation Solutions to Heart of America Surgery Center in Kansas City, Kansas on December 4, 2003.

54. Respondent's invoice number 1016626229 shows the distribution of an Irrigation Solution and Lactated Ringers IV Solution to Physician's Surgery Center in Rolla, Missouri on December 4, 2003.

55. Respondent's invoice number 1016648194 shows the distribution of Dextrose in Normal Saline IV Solution to Logan Manor Nursing Home in Logan, Kansas on December 6, 2003.

56. Respondent failed to renew its distributor license on or before November 30, 2003 and it became null and void at that time.

57. Respondent continued to distribute prescription only product while its license was expired.

58. Respondent's failure to renew its license by the renewal deadline of November 30, 2003 and to continue to distribute prescription only product while its license was expired is in violation of Section 338.333.1, RSMo (2000) states in pertinent part:

> 1. No person or distribution outlet shall act as a wholesale drug distributor or pharmacy distributor without first obtaining license to do so from the Missouri board of pharmacy and paying the required fee. . . . No license shall be issued or renewed for a wholesale drug distributor or pharmacy distributor to operate unless the same shall be operated in a manner prescribed by law and according to the rules and regulations promulgated by the board of pharmacy with respect thereto. Separate licenses shall be required for each distribution site owned or operated by a wholesale drug distributor or pharmacy distributor.

59. Respondent's opening for business its operation as a wholesale drug distributor in a new location prior to inspection and approval of the Board is in violation of 4 CSR 220-5.020(6) which states:

> (6) If an individual or business entity operating a drug distributor facility changes the location of the facility either within the existing facility (structure) or to a new facility (structure), the facility shall not open for business at the new location until the board, its duly authorized agent or the Food and Drug Administration has inspected the premises of the new location and approved it and the facility has been in compliance with all state and federal drug laws pertaining to drug distribution. Upon the approval and receipt of a change of location fee, the board shall issue a permit authorizing operation of a facility at the new location and the permit shall bear the same number as the previous license. However, the license remains valid if the facility address changes, but not the location, and an amended license will be issued without charge under these circumstances.

Joint Conclusions of Law

60. Cause exists for Petitioner to take disciplinary action against Respondent's license under § 338.353(1), RSMo (Supp. 2002) which provides:

> 1. The board of pharmacy is hereby authorized and empowered, when complaints, examinations or inspection of wholesale drug distributor or pharmacy distributor disclose to the board that a wholesale drug distributorship or pharmacy distributorship is not being operated or conducted according to such legal rules and regulations and the laws of Missouri or any other sate or the federal government with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621, RSMo, charging the holder of a license to operate a drug distributorship or pharmacy wholesale operation constituting grounds for discipline in accordance with section 338.055.

61. Cause exists to discipline Respondent' license as a drug distributor pursuant to the

provisions of § 338.055, RSMo (Supp. 2002) which provides in pertinent part:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his certificate of registration or authority, permit or license for any one or any combination of the following causes:
>
> * * *
>
> (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter.
>
> * * *
>
> (12) Failure to display a valid certificate or license if so required by this chapter or any rule promulgated hereunder.
>
> * * *
>
> (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government.

Joint Agreed Disciplinary Order

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of §621.045.3, RSMo (2000):

1. Respondent's drug distributor license shall be placed on PROBATION for five (5) years pursuant to the provisions of Chapters 338 and 620, RSMo. During the period of

probation, Respondent will be entitled to operate as a drug distributor pursuant to Chapter 338, RSMo provided Respondent adheres to the following terms of probation:

A. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months, beginning six (6) months after this Order/Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of this disciplinary order.

B. Respondent shall pay all required fees for licensing to the Board and shall renew its license prior to October 31 for each licensing year.

C. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

D. If, after disciplinary sanctions have been imposed, Respondent ceases to keep its Missouri license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

E. The parties to this Order/Agreement understand that the Board of Pharmacy will maintain this Order/Agreement as an open record of the Board as provided in Chapters 338, 610 and 620, RSMo.

2. Upon the expiration of said discipline, Respondent's license as a drug distributor in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary

hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent.

3. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

4. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

5. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

6. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and

attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to § 536.087, RSMo, or any claim arising under 42 U.S.C. § 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

_____ REQUESTS

_____ DOES NOT REQUEST

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S LICENSE TO OPERATE AS A DRUG DISTRIBUTOR.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's license and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's license. Effective the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's license, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the

Settlement agreement goes into effect 15 days after the document is signed by the Board's Executive Director.

RESPONDENT

MEDLINE INDUSTRIES, INC.

By: _____

Pete Furlong
Corporate Vice President
Quality Assurance/Regulatory Affairs

Date: July 1, 2005

PETITIONER

MISSOURI BOARD OF PHARMACY

By: _____

Kevin Kinkade
Executive Director

Date: 7-19-05

HUSCH & EPPENBERGER, LLC

By: _____

Harvey M. Tettlebaum
235 East High Street
P.O. Box 1251
Jefferson City, MO 65102-1251
Telephone: 573/635-9118
Fax: 573/634-7854

Attorneys for Medline Industries, Inc.

NEWMAN, COMLEY & RUTH P.C.

By: _____

Robert K. Angstead #37795
601 Monroe, Suite 301
P.O. Box 537
Jefferson City, MO 65102-0537
Telephone: 573/634-2266
Fax: 573/636-3306

Attorneys for Missouri Board of Pharmacy

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	12/07/2006	GA	Lithia Springs	Douglas

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
N/A	Florida Department of Health

Reason/Charge
Medline's Florida Certified Designated Representative unexpectedly resigned.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Florida Department of Health/ Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries Inc. distribution center at 9101 Riverside Pkwy Lithia Springs, GA 30122 Non-Resident FL Permit (FL # 23:1470) suspended for operating without a FL Certified Designated Representative. The CDR resigned unexpectedly. Upon receipt of the notice of intent to suspend, Medline stopped all shipments into the state of FL. Permit was reinstated upon hiring of a new licensed Florida CDR.

Corrective Actions:
Qualified FL Certified Designated Representative hired for facility. Medline implemented a policy requiring all FL licensed distribution centers to maintain a backup Florida Certified Designated Representative on staff.

Original Signature (electronic, copies or stamps not accepted)

07/30/26
Date

Medline Industries, Inc. One Medline Place Mundelein, Illinois 60060-4486 1.800.950.0128 Fax 1.847.949.2643

Corporate Quality Assurance/Regulatory Affairs

December 11, 2006

Ms. Rebecca R. Poston, R.Ph.
Executive Director
Drugs, Devices & Cosmetics Program
Florida Department of Health
4052 Bald Cypress Way
Tallahasee, FL 32399

RE: Prescription Drug Wholesaler Permit No. 23:01470

Dear Ms. Poston,

We have received the communication regarding the suspension of Prescription Drug Wholesaler Permit N. 23:01470. Pursuant to our communication with Rebecca Burnett on November 28, we have blocked applicable shipments from this location into Florida and they are being supplied by a properly permitted facility.

We are in the process of qualifying a replacement designated representative for this location. We hope to have this completed within the next 60 days.

Please note that Mr. Andy Stolarski is retiring and should no longer be listed as a contact for this location. Please direct any questions regarding this facility to
Ms. Lara Simmons
Corporate Director, Regulatory Affairs
One Medline Place
Mundelein, IL 60060
Phone: 847.837.2759
Fax: 847.837.2787
Email: LSimmons@Medline.com.

Sincerely,

Lara N. Simmons
Corporate Director, Regulatory Affairs

Dynacot Division
ISO9001
QUAL 1998
EN46001
MED2001/7665

Medline Division
ISO9001
QUAL
EN46001
MED2001

OMI

CERTIFIED MAIL/RETURN RECEIPT REQUESTED

December 7, 2006

Andrew Stolarski
Vice President of Operations
Medline Industries, Inc.
9101 Riverside Parkway
Lithia Springs, GA 30122

RE: Prescription Drug Wholesaler Permit No. 23:01470

Dear Mr. Stolarski:

This letter serves as notification that the department intends to suspend permit no. 23:01470 issued to Medline Industries, Inc. as an Out of State Prescription Drug Wholesaler based upon the following facts, grounds and considerations:

Section 499.067(1)(a), Florida Statutes (F.S.), authorizes the department to deny, suspend, or revoke a permit if it finds that there has been substantial failure to comply with § 499.001-499.081, F.S., or Chapter 465, Chapter 501, or Chapter 893, the rules adopted under any of those sections or chapters, any final order of the department, or applicable federal laws or regulations or other state laws or rules governing drugs, devices, or cosmetics. The department may also suspend a permit if the applicant has not met the requirements for the permit.

Pursuant to s. 499.012(11)(a), F.S., each establishment that is issued an initial or renewal permit as a prescription drug wholesaler or an out-of-state prescription drug wholesaler must designate in writing to the department at least one natural person to serve as the designated representative of the wholesaler. Such person must have an active certification as a designated representative from the department and must also meet the requirements of Section 499.012 (11) (d) F.S.

Pursuant to s. 499.012(11)(f), F.S., a wholesale distributor may not operate under a prescription drug wholesaler permit or an out-of-state prescription drug wholesaler permit for more than 10 business days after the designated representative leaves the employ of the wholesale distributor, unless the wholesale distributor employs another designated representative and notifies the department within 10 business days of the identity of the new designated representative. Mr. David L. Magruder, the designated representative identified for permit no. 23:01470 has resigned his position. We have not received a "Notification of Designated Representative" form identifying a certified individual to replace him. As a result Medline Industries, Inc. does not have a designated representative as required by s. 499.012(11), F.S.

Pursuant to s. 499.012(11)(b)4., F.S., to be certified as a designated representative, a person must receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and ss. 499.001-499.081 and the rules adopted by the department governing the wholesale distribution of prescription drugs.

Accordingly, and pursuant to the above referenced facts and law, the department hereby intends to suspend permit no. 23:01470 issued to Medline Industries, Inc. as an Out of State Prescription Drug Wholesaler because you have not complied with s. 499.012(11)(f), F.S. and otherwise do not have a designated certified representative on file with the Department that meets the requirements of Section 499.012 (11) F.S. which is a substantial failure to comply with ss. 499.001 – 499.081, F.S. and is a failure to meet the requirements for the permit, for which the suspension is authorized pursuant to Sections 499.067 (1) (a); 499.067 (1) (b) 2. F.S.

Therefore, the department concludes that Medline Industries, Inc. no longer meets the requirements to continue to operate as an Out of State Prescription Drug Wholesaler in Florida and the permit will be suspended until you have designated in writing to the department a person with an active certification to serve as a designated representative who meets the requirements of Section 499.012 (11) F.S.

NOTICE OF RIGHTS TO HEARING AND APPEAL

You have the right to request an administrative hearing pursuant to sections 120.569 and 120.57, F.S., if you wish to challenge the intended agency action to suspend your permit. Such proceedings are governed by sections 120.569 and 120.57, F.S., and Rules 28-106 and 28-107, Florida Administrative Code. Request for a hearing, formal or informal, must comply with Rule 28-107.004, Florida Administrative Code.

You have the right to be represented by counsel or other qualified representative, at your expense; to present evidence and argument; to call and cross-examine witnesses; and to have subpoena and subpoena duces tecum issued on your behalf if a hearing is requested.

A petition for administrative hearing must be in writing and must be received by the Agency Clerk for the Department, within twenty-one (21) days from the receipt of this complaint. The address of the Agency Clerk is 4052 Bald Cypress Way, BIN # A02, Tallahassee FL 32399-1703. The Agency Clerk's facsimile number is 850-410-1448.

Mediation is not available as an alternative remedy.

Your failure to submit a petition for hearing within 21 days from receipt of this complaint will constitute a waiver of your right to an administrative hearing, under Florida Administrative Code Rule 28-106.111 and this complaint shall become a "final order".

Should this correspondence become a final order, a party who is adversely affected by it is entitled to judicial review pursuant to s 120.68, F.S. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings may be commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by the filing fees required by law, with the Court of Appeal in the appropriate District Court. The notice must be filed within 30 days of rendition of the final order.

Sincerely,

Rebecca R. Poston, R.Ph.
Executive Director
Drugs, Devices, & Cosmetics Program

RP/rb

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	02/08/2008	FL	Gainesville	Alachua

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2007-37412	Florida Department of Health

Reason/Charge
Inspection Deficiencies

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Florida Department of Health / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. distribution center at 2708 NE Waldo Rd., Gainesville, FL 32609 FL Permit (FL # 22:1022) suspended for violations identified during a Florida BOP facility inspection. Medline, through Counsel, addressed the issues raised in the inspection and established that the suspension was unjustified. The suspension was lifted 3 days later on January 22, 2008. Medline Industries, Inc. entered into a settlement agreement on 02/08/2008 with the FL Department of Health to resolve all issues related to the case.

Corrective Actions:
Medline conducted a thorough review of its policies and procedures and implemented an internal auditing program to ensure that all distribution centers comply with internal policies and procedures and state and federal regulations.

Original Signature (electronic, copies or stamps not accepted)

07/30/24
Date

Final Order No. DOH-08-0203-S -MQA
FILED DATE - 2-8-08
Department of Health
By: Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

Case No.: 2007-37412

vs.

MEDLINE INDUSTRIES, INC.,

Respondent.
_____/

FINAL ORDER

In this matter, the Florida Department of Health is proceeding under the Florida Drug and Cosmetics Act, Chapter 499, Florida Statutes. The Parties request a final order adopting their settlement agreement.

Being fully advised, the Parties' request is granted. On or about February 8, 2008, the Parties fully executed their "Settlement Agreement for Final Order", which is incorporated by reference. The "Settlement Agreement for Final Order" is approved, and the parties are directed to comply with it.

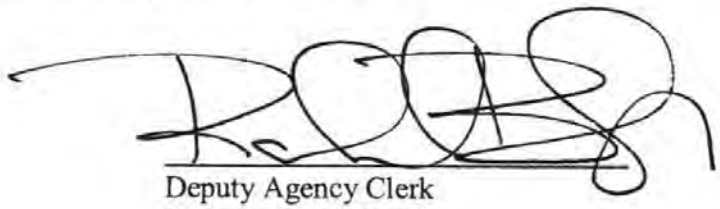
DONE and **ORDERED** this 8TH day of February 2008, in Tallahassee, Leon County, Florida.

ANA M. VIAMONTE ROS, M.D., M.P.H.
STATE SURGEON GENERAL

By: for PAUL METTS, C.P.A., M.H.A.
DEPUTY SECRETARY

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been furnished via U.S. Mail, or fax delivery to: Edwin Bayo, Esq., Attorney for MEDLINE INDUSTRIES, INC., at Metzger, Grossman, Furlow & Bayo, L.L.C , 1408 North Piedmont Way, Tallahassee, Florida 32308, 850.385.4240 (facsimile) and via interoffice mail to Lynne A. Quimby-Pennock, Assistant General Counsel, Department of Health, 4052 Bald Cypress Way, Bin #C-65, Tallahassee, Florida 32399-3265 this 8 day of February 2008.



Deputy Agency Clerk
Department of Health
4052 Bald Cypress Way, Bin C-01
Tallahassee, Fl. 32399-3251

DELEGATION OF AUTHORITY
to
Deputy Secretaries and Chief of Staff

A. In accordance with the authority created in Sections 20.05(1)(a) and (b) and 20.43, Florida Statutes and vested in me as State Surgeon General for the Department of Health, the following authority is delegated:

1. Take all actions required for the effective direction and administration of the Department of Health in accordance with applicable Florida Statutes (F.S.), Florida Administrative Code (F.A.C.), and department policies.

2. In the absence of the State Surgeon General, each deputy is delegated authority to sign as the agency head or represent the State Surgeon General at any meetings within their respective areas, unless there is a specific delegation of authority.

3. In the absence of a deputy, the other deputies are delegated the authority to take all actions required for the effective administration and operation of that respective area, unless there is a specific delegation of authority.

4. Act as a hearing officer in proceedings required by Section 120.54(3)(c), F.S., (Hearings) and to enter any order in connection therewith.

5. Enter final orders in proceedings under Section 120.57, F.S. (Additional Procedures Applicable to Hearings).

6. Authorize policies and procedures within your respective areas; however, all department-wide policy and procedure changes that affect or have an impact on other areas such as statewide computer systems, standard audit practices, and workload for the Division of Administration, shall be coordinated with the appropriate division director. **The State Surgeon General approves and signs all department policies.**

7. Approve contracts (revenue and expenditure) and purchase orders $1 million or more. This authority may not be redelegated. **Exception: Fixed Capital Outlay contracts, change orders and additional FCO services authorizations are delegated to the Director of Administration, who may only redelegate to the Chief of General Services or Administrator of Design and Construction.**

8. Approve all grant applications and carryover requests greater than $250,000. Bureau of Revenue Management approval required for Central Office grant applications prior to submission to the awarding agency.

9. Approve the hiring of Senior Management Service and Selected Exempt Service employees at a bureau chief level or higher pursuant to Chapter 60L-33, F.A.C., and department policy.

10. Grant Career Service employees salary additives in excess of 10% in accordance with Rule 60L-32.0011, F.A.C., and department policy.

11. Grant employees an increase to base rate of pay in excess of 10%in accordance with Rule 60L-32.0011, F.A.C., and department policy.

12. Approve appointments of employees previously dismissed from the department or other state agency. Approve appointments of employees who resigned from the department or other state agency while under investigation; or pursuant to a settlement agreement; or in lieu of dismissal.

13. Approve exemptions under Section 435.07, F.S., for persons disqualified from employment under Section 435.04, F.S.

14. Issue decisions on collective bargaining grievances at Step 2, in accordance with the Florida Statutes, department policy, and the applicable collective bargaining agreement.

15. Authorize and approve out-of-state travel.

16. Approve Emergency Suspension Orders and Emergency Restriction Orders during the absence of the State Surgeon General.

17. Approve core contracts under Chapter 154, F.S., with the local Board of County Commissioners.

B. Exceptions to this authority, which require the approval of the State Surgeon General are:

1. All changes to organization structure, functions, and programs involving the moving of positions or units between budget entities and divisions, or any action requiring the Department of Management Services and the Governor's Office of Policy and Budget approval.

2. Appointment or dismissal of county health department directors/administrators, children's medical services medical directors, division directors, or office directors.

C. This authority may be modified for specified periods of time as desired by the State Surgeon General.

D. These delegations may not be redelegated without the approval of the State Surgeon General.

8/6/07
Effective Date

Ana Maria Viamonte Ros
Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General
Department of Health

STATE OF FLORIDA
FLORIDA DEPARTMENT OF HEALTH
Medline Industries, Inc.
Case #2007-37412

SETTLEMENT AGREEMENT FOR FINAL ORDER

IT IS AGREED and STIPULATED by and between the State of Florida, Department of Health and MEDLINE INDUSTRIES, INC., that:

1. The Department of Health, through its Division of Medical Quality Assurance, Drugs, Devices and Cosmetics Program, (referred to as "the Department", 4052 Bald Cypress Way, Bin C-04, Tallahassee, Florida 32399 is responsible for, among other duties, under the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes (the Act) and the rules adopted there under, Rule 64F12 Florida Administrative Code, the regulation and permitting of prescription drug manufacturing and wholesaling within and into Florida.

2. The Department has investigated MEDLINE INDUSTRIES, INC., (referred to as "Medline") which holds a prescription drug wholesale permit, permit number 22:1022, located at 2708 NE Waldo Road, Gainesville, Floirda32609-3323.

3. The Department investigated Medline during the week of November 26, 2007, and found Medline to be operating in violation of Chapter 499, Florida Statutes (F.S.). The specific violations alleged include:

a. s. 499.005(1), & (4) F.S., and 499.069(1), F.S. in violation of s. 499.0121(1) F.S., and Rule 64F-12.014(4) Florida Administrative Code (F.A.C.) - holding or offering for sale any drug, device or cosmetic that is adulterated or

misbranded or has otherwise been rendered unfit for human or animal use. Establishment to be maintained in a clean and orderly manner to prevent the product from becoming contaminated with filth or injurious to health. (The surplus warehouse was unclean with spiders, spider webs, dead insect bodies, bird feces/droppings and feathers therein.)

b. ss. 499.005(1) & (4), F.S., in accordance to s. 499.006(9), F.S., holding for sale adulterated medical devices on its inventory shelves through a failure to quarantine outdated medical devices.

c. ss. 499.005(4), 499.0121, F.S. & Rules 64F-12.013, & 64F-12.015(7)(a) F.A.C., - Improper Prescription drug storage, lack of climate control.

d. s. 499.0121(3), F.S. – Failure to notify the Department of all prescription drug sources.

e. s. 499.005(14), F.S. – Receiving prescription drugs from an unauthorized source.

f. ss. 499.005(18), 499.0121(6), F.S., and Rules 64F-12.012(5), 64F12.001(2), and 64F-12.012(3)(a), F.A.C., – failure to have pedigrees readily available for inspection.

g. s. 499.0121(7), F.S., inadequate SOP (standard operating procedures) or P&P (policy and procedures), or failing to follow them.

h. s. 499.005(24), F.S., distribution of legend devices to the ultimate user without a prescription or order from practitioner.

i. s. 499.005(4), F.S., in violation of s. 499.0121(2), F.S.,- unrestricted access to prescription drugs in that prescription drugs, devices and/or cosmetics are left on a loading dock for pick-up/delivery, but the area does not have restricted access.

4. On or about November 27 and/or 28, 2007, seizure orders were placed on numerous items in Medline's surplus warehouse and one pallet of product within the climate-controlled warehouse.

5. On January 22, 2008, an Order of Emergency Restriction of Permit was issued by State Surgeon General, Ana M. Viamonte Ros, M.D., M.P.H., restricting the specific use of the facility.

6. A Final Order in this case will incorporate the following agreed upon terms and conditions:

a. All items under the seizure order that contain prescription drug products shall be destroyed at Medline's expense at a Florida Chapter 499, F.S., permitted facility; all other seized items shall be destroyed by Medline at Medline's expense. Within ten (10) days of the destruction, Medline shall submit documentation detailing the destruction of said items to the Compliance Officer of the Florida Drug, Device and Cosmetic Program, at 4042 Bald Cypress Way, MQA/HSE, Tallahassee, Florida 32399.

b. All products remaining at Medline's facility that were received from J & L Medical, Inc., located at 784 Old Checker Ct.,

Buffalo Grove, Illinois, between June 2007 through November 27, 2007, shall be destroyed at Medline's expense at a Florida Chapter 499, F.S., permitted facility, or if the products do not contain prescription drugs shall be destroyed by Medline at Medline's expense. Within ten (10) days of the destruction, Medline shall submit documentation detailing the destruction to the Compliance Officer of the Florida Drug, Device and Cosmetic Program, at 4042 Bald Cypress Way, MQA/HSE, Tallahassee, Florida 32399.

c. Medline shall pay a fine of FIFTY THOUSAND DOLLARS ($50,000.00) to the Florida Drug, Device and Cosmetic Trust Fund. Said payment shall be by certified check, cashier check or money, and shall accompany this executed Settlement Agreement. Said check shall be made payable to the Florida Drug, Device and Cosmetic Trust Fund.

d. The Order of Emergency Restriction, entered by the Department on January 22, 2008, shall be lifted upon the filing of the Final Order adopting and accepting the terms of this Settlement Agreement.

e. Medline shall undergo quarterly inspections by the Department at Medline's expense for one (1) year from the issuance of the Final Order, to ensure proper compliance with Chapter 499, Florida Statutes and the rules thereto. The Department shall provide an invoice for the inspection that shall be paid within thirty (30) days of receipt by Medline. Said payment shall be sent to the Compliance Officer of the

Florida Drug, Device and Cosmetic Program, at 4042 Bald Cypress Way, MQA/HSE, Tallahassee, Florida 32399. The Department retains the authority to enter the permitted facility/warehouse at any time to conduct inspections/investigations as authorized by Florida law.

f. Medline shall conduct a training program, within thirty (30) days of the execution of this Settlement Agreement For Final Order, for its facility employees educating the employees on the requirements of Chapter 499, Florida Statutes and the applicable rules. Within ten (10) days of the training, Medline shall submit documentation detailing the training to the Compliance Officer of the Florida Drug, Device and Cosmetic Program, at 4042 Bald Cypress Way, MQA/HSE, Tallahassee, Florida 32399.

g. Medline shall comply with all applicable Federal and state law and rules, including but not limited to Chapter 499 Florida Statutes, and its applicable rules. Medline shall comply with all pedigree and audit trail requirements for all prescription drugs purchased, held and /or distributed by Medline, including the authentication of any prescription drugs received. Medline shall ensure that any automated pedigree system employed, shall satisfy the requirements of Chapter 499, F.S. and the applicable rules thereto.

h. Medline shall maintain its facility in a clean, orderly and pest/bird free environment.

7. By execution of this Settlement Agreement For Final Order and by the filing of the subsequent Final Order in this cause, the Department and Medline intend to and do resolve all issues pertaining to the above referenced investigation.

8. Medline neither admits nor denies the violations allege in the inspection/investigation reports generated by the Department's investigators in this cause.

9. Upon entry of the Final Order adopting this Agreement, the Department will not seek further disciplinary action against Medline based on any of the alleged violations described in the above listed case number. However, if there are future violations of Chapter 499, F.S., or the rules adopted thereto, the above listed case will be considered aggravating circumstances and will be construed as previous violations for purposes of assessing the amount of the fine to be levied pursuant to section 499.066(3)(c), F.S.

10. Medline voluntarily enters into this Settlement Agreement for Final Order and waives the right to a hearing in this matter and all further proceedings to which it may be entitled by law or administrative rules. Medline hereby knowingly and voluntarily waives all right to challenge or to contest this Settlement Agreement or the Final Order issued by the Department in any forum now or in the future available to them, including the right to any administrative proceeding,

circuit or federal court action, or any appeal. Both parties agree not to appeal this Settlement Agreement or the Final Order to be issued in this matter.

11. The signatories hereto represent that they have read this Agreement and are authorized to execute it on behalf of their respective principals and as duly designated representatives, to fully bind such principals, as well as the Parties successors and assigns. The terms of this Agreement are effective on the date of the last signature below. The original will be filed with a Final Order with the Department Clerk. Each signer will receive a copy of this Agreement.

12. This document is a public record and contains information that is routinely published by the Department. Upon the filing of this Agreement and entry of a Final Order by the Department the existence of the above reference case number and all matters therein are no longer confidential and exempt from public disclosure. All documents or records created or submitted for compliance issues shall be a public record when filed with the Department.

13. Each party to this proceeding shall bear its own costs and attorney fees.

14. The absences of a prohibition specifically listed in this Agreement shall not be construed as permission to engage in any activity that otherwise is in violation of section 499.001-499.081, Florida Statutes, or the rules promulgated thereunder.

15. Upon the filing of this Settlement Agreement for Final Order, the parties, as well as any person who may claim by or through them, hereby waive,

release and discharge the other, and any of their employees, attorneys, agents or representatives from all claims arising out of any act or omission related to the investigation and settlement of this matter. This release applies to any and all claims of any kind, whether known or unknowns and whether direct, indirect or derivative.

16. Upon execution of this Agreement the State Surgeon General or her designee will issue a Final Order incorporating the terms hereof.

17. The parties agree that should any legal dispute arise concerning enforcing the terms of this Agreement, venue shall be in Leon County, Florida and this Agreement shall be interpreted in accordance with applicable Florida law.

WHEREFORE the Parties request a final order adopting this Agreement as final agency action.

For: Medline Industries, Inc.,

Lara N. Simmons February 7 2008
Lara N. Simmons
Corporate VP for QA and RA
Authorized Representative, Medline Industries, Inc.,

For the Department of Health - Drug, Device and Cosmetic Program
4052 Bald Cypress Way,
Tallahassee, Florida 32399, 850.245.4031 , 850.245.4682 Fax

Daisy King for February 8 2008
Rebecca Poston, R.PH
Executive Director
Florida Drug, Device & Cosmetic Program
Department of Health

Medline Industries, Inc., Case #2007-37412

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	05/01/2008	LA	Covington	St. Tammany Parish

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2008006	Louisiana Board of Wholesale Drug Distributors

Reason/Charge
Customer Licenses

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
LA Board of WDD/ Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries Inc. distribution center at 149 New Camellia Blvd. Covington, LA 70433 (LA #4318) cited for failure to properly maintain copies of current customer licenses on-site. Licenses were maintained by Medline's Regulatory team at corporate headquarters. Medline entered a consent decree effective 05/01/2008 to resolve the alleged violation.

Corrective Actions:
Medline implemented digital storage of customer licenses to allow for on-demand access by distribution centers.

Original Signature (electronic, copies or stamps not accepted)

07/30/26
Date

LOUISIANA BOARD OF
WHOLESALE DRUG DISTRIBUTORS

MEDLINE INDUSTRIES, INC. Covington, LA LICENSE NO. 4318	CONSENT ORDER ADMINISTRATIVE CASE NO. 2008006

In review of evidence presented to the Louisiana Board of Wholesale Drug Distributors (the "Board") addressing specific violation(s) of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors by MEDLINE INDUSTRIES, INC., Covington LA facility (the "Respondent", "Licensee"), acting herein by its authorized agent, to-wit: "Copies of current licenses for customers who are authorized by law or regulation to procure or possess drugs or devices shall be maintained for all customers that are shipped or sold drugs or devices. If customer licenses are maintained off site, a list of customer names, addresses, licenses numbers, and license expiration dates shall be maintained for all customers that are shipped or sold drugs or devices.", La. R.S. Title 37, Chapter 54, Section 3467, and LAC, Title 46, Part XCI, Section 311.D and "violating provisions of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors", La. R.S. Title 37, Chapter 54, Section 3474.1 and LAC Title 46, Part XCI, Section 107.

Upon consideration of the evidence presented to the Board, this Consent Order is voluntarily entered into by and between Respondent and the Board. Respondent acting through its authorized agent, hereby waives formal Notice of and its attendance at the Evidentiary Hearing, for presentation of the Consent Order to the Board. However, as a condition precedent to submission of the proposed Consent Order to the Board, Respondent hereby acknowledges and understands that information may be presented to the Board with regards to the details of the case for the Board to understand the circumstances. It is further acknowledged and understood by Respondent that in the event the Board is not agreeable to enter into the proposed Consent Order and an Administrative Hearing is ultimately conducted, the Board which will be presiding over the case will possibly have heard information which may later be submitted at the scheduled hearing. If such hearing occurs, Respondent waives any right that it may have to recuse or remove any or all members of the Board for the purposes of an Administrative Hearing in the event the proposed Consent Order is not accepted by the Board, or if Respondent withdraws his consent to the proposed Consent Order prior to its final approval by the Board. Furthermore, Respondent has had the opportunity to, or has in fact consulted with, legal counsel with regards to the Consent Order and the waivers contained herein.

FINDINGS OF FACTS

1. Respondent possesses Louisiana License No. 4318 issued by the Board to wholesale distribute legend drugs and devices in the State of Louisiana. Such license was in effect on 3/5/2008 through the date of the evidentiary hearing in this matter.

2. Pursuant to LAC 46:XCI.311.D, a licensee is required to maintain copies of current licenses for customer who are authorized by law or regulation to procure or possess legend drugs or devices for all customers that are shipped or sold legend drugs or devices; if these license copies are maintained off site, a list of customers with customer names, addresses, license number, and license expiration dates shall be maintained on site for all customers shipped or sold legend drugs or devices.
3. On 3/5/2008, an inspection was conducted by the Board's representative which revealed that copies of customer licenses were not at the Covington LA facility. A verbal request to provide a customer listing which should be maintained at the Covington LA facility was made. The customer license list was not available.
4. Information was thereafter submitted by Respondent to the Board's inspector as per the inspector's request. In review of a customer listing ("Pedigree List") as provided by the Respondent, the inspector requested copies of customer licenses for 15 of the customers listed. Verbal explanation was given was that customer licenses are verified and the customer is entered electronically into the system as an authorized recipient but that no hard copy of the customer license is being maintained.
5. Respondent's conduct in failing to maintain customer license documents and/or a customer listing at the Covington LA site is in violation of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors, specifically LAC 46:XCI.311.D.
6. Disciplinary sanctions and/or fines are applicable against Respondent in accordance with the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors.

CONCLUSIONS OF LAW

1. It is unlawful for Respondent, as a licensee to wholesale distribute legend drugs and devices, to not maintain current customer license documents and/or a current customer listing on-site. LAC 46:XCI.311.D.
2. It is unlawful for Respondent, as a licensee to wholesale distribute legend drugs and devices, to violate any of the provisions of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors. La. R.S. 37:3474.1 and LAC 46:XCI.101.
3. Respondent's violations of the provisions of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors constitute lawful grounds for the Louisiana Board of Wholesale Drug Distributors, upon due notice of hearing and proof of such violations, to assess a fine, revoke, suspend, or otherwise discipline Respondent's license as provided by law. La. R.S. 37:3474.1 and LAC 46:XCI.701 et seq.

DECISION

4. Respondent is hereby assessed a fine in the amount of $2,000 for its failure to properly maintain copies of current licenses for customers shipped or sold legend drugs or devices and/or a customer listing on site. Said fine to be paid on the effective date of

this Consent Order. No practice restrictions are placed on Respondent's license issued by the Board.

5. The existence and terms of this Consent Order will not be confidential or privileged information in accordance with the laws regarding public records.
6. Respondent hereby releases the Board, its representative, and attorney from any obligations or liability in their endeavors to administer this Consent Order.
7. The effective date of this Consent Order shall be such date it is accepted by the Board.
8. Respondent, through its authorized agent, declares that, before signing this Consent Order, it has carefully read this document, and it knows and understands the contents thereof, it signs it as an act of it own free will, it understands its meaning and effect, it has been given the opportunity to consult with an attorney, it voluntarily waives all rights to formal notice and a formal public hearing, as well as its appearance at the proceedings, and it consents to this Consent Order.

THUS DONE AND PASSED, on the 1 date of May, 20 08 at the City of Mundelein, Parish/County of Lake, Louisiana/Illinois, in the presence of the two undersigned competent witnesses, who hereunto sign their names with Appearer and me, Notary, after due reading of the whole.

WITNESSES

Brenda Thompson

Deborah Kluczek

MEDLINE INDUSTRIES, INC.
Covington LA

Signature of Authorized Agent

Lisa M. Simms

Print Name of Authorized Agent

Notary Public

OFFICIAL SEAL
SUSAN MILLER
Notary Public - State of Illinois
My Commission Expires Jul 16, 2011

LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS
12046 Justice Avenue, Suite C
Baton Rouge, LA 70816
(225) 295-8567 Fax (225) 295-8568 lsbwdd@bellsouth.net www.lsbwdd.org

April 28, 2008

Lara N. Simmons, VP-QA/RA
MEDLINE INDUSTRIES, INC.
One Medline Place
Mundelein, IL 60060

RE: Louisiana License No. 4318
Administrative Docket No. 2008006

CERTIFIED MAIL
No. 7007 3020 0000 4431 6851
Return Receipt Requested

Dear Lara Simmons:

As you may recall, the Board is mandated by law to license and regulate the wholesale distribution of legend drugs and devices in Louisiana in accordance with the Louisiana Revised Statutes and Louisiana Administrative Codes for wholesale drug distributors. This letter will acknowledge receipt of your response dated 4/3/2008. This letter is also intended to respond to any inquiries you may have regarding the deficiencies found during the inspection which occurred on 3/5/2008 at MEDLINE INDUSTRIES, INC.'s Covington LA distribution facility.

Pursuant to the Louisiana Revised Statutes and Louisiana Administrative Codes, specifically LAC 46:XCI.311.D, a licensee should maintain copies of current licenses which authorizes a customer to procure and possess legend drugs and devices. If these customer licenses are maintained off site, a list of customers including customer names, addresses, license number, and the license expiration dates shall be maintained for all customers that are shipped or sold drugs or devices.

On 3/5/2008, the Board's inspector discovered that copies of customer licenses which authorize the customer to procure and possess legend drugs/devices or a listing of customers' license information were not being maintained at the Covington LA facility.

A verbal request was made by the inspector of a customer list which should have been maintained at the Covington LA facility. After receiving and reviewing a copy of the customer list, as referred to by Medline as their "Pedigree List", the inspector requested copies of 30 customer licenses from the listing. Of the requested customer license copies, the inspector found that 70% of the licenses requested were either not acceptable licenses or were not available.

It is evident that MEDLINE INDUSTRIES, INC. was in violation of LAC 46:XCI.311.D at the time of the inspection on 3/5/2008. The Louisiana Revised Statutes and Louisiana Administrative Codes for wholesale drug distributors, more particularly LA RS 37:3474.1, provides that, after due notice and hearing, MEDLINE INDUSTRIES, INC.'s license may be sanctioned and/or it may be assessed a fine for its actions or omissions. Fines alone may include an assessment of $1,000 per violation

Bob Brooks, Chairman
Michael Crews, Vice-Chairman
Randall Brooks, Secretary-Treasurer
John Diggle, Executive Director-Inspector
Darrell Tate, Board Member
Wayne Gremillion, Board Member
Eric Vidrine, Board Member
Kimberly B. Barnes, Executive Assistant

per day. It is the Board's objective to regulate the industry by correcting behavior. Such is accomplished by imposing sanctions for wrongful conduct.

It is hoped that the above detailed violation(s) as corrected will not occur in the future. Therefore, in an effort to amicably resolve the issues regarding the violation(s) which did occur, I, as the Board's appointed investigating/compliance officer, extend an offer to you which would impose a total fine of $2,000. This proposed sanction does not impose any restrictions on MEDLINE INDUSTRIES, INC.'s license.

If MEDLINE INDUSTRIES, INC. is agreeable to these terms, I have enclosed a Consent Order for your review and execution. Please have an authorized representative for your company sign the Consent Order in front of a Notary and two witnesses. Return the original, executed Consent Order along with a check made to the Louisiana Board of Wholesale Drug Distributors in the amount of the $2,000 fine to the Board's office within fifteen (15) days of receipt of this letter. You and/or a company representative will not be required to attend the evidentiary hearing at which the executed Consent Order will be presented to the full Board for acceptance, however you and/or another representative are welcome to attend.

In the event MEDLINE INDUSTRIES, INC. is not agreeable to this amicable resolution and wishes to contest the investigative findings in a hearing before the full Board, it has the right to do so. If such occurs, the current offer being proposed in this letter will no longer be viable.

We would like to bring this matter to disposition either by this amicable resolution or the pursuit of a formal hearing against MEDLINE INDUSTRIES, INC. before the Board at the next scheduled Board meeting. To do so, either way, we will need to prepare the necessary paperwork with all resolution documents. Again, please respond to this offer either by returning the executed Consent Order and fine payment or by written request for an administrative hearing. If your response is not received at the Board office within fifteen (15) days of receipt of this letter, the Board will begin steps towards the formal hearing with the issuance of subpoenas for witnesses and records.

We wish to keep an open line of communication with you. Please contact the Board office in the event you have any questions. Thank you for your cooperation in this matter.

Respectfully,

Wayne Gremillion
Board Member/Compliance Officer

kbb
Encl: Consent Order
File
c.c. Gregg C. Stoeckel, Covington LA

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	07/08/2008	HI	Waipahu	Honolulu

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
PHA 2008-71-L	Hawaii Department of Commerce and Consumer Affairs

Reason/Charge
Late Discipline Reporting

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
HI DCCA / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. distribution center at 94-1420 Moaniani St., Waipahu, HI 96797 (HI # PWD 115) entered a settlement agreement and placed on probation for 5 years for failure to report disciplinary actions within 30 days. Medline submitted all required notices but missed the 30-day deadline. The probationary period ended in August 2013.

Corrective Actions:
Medline implemented a policy and procedure to notify licensing boards of disciplinary actions within the required reporting timelines.

Original Signature (electronic, copies or stamps not accepted)

07/30/26
Date

LINDA LINGLE
GOVERNOR

JAMES R. AIONA, JR.
LT. GOVERNOR

LAWRENCE M. REIFURTH
DIRECTOR
DEPARTMENT OF COMMERCE AND
CONSUMER AFFAIRS

JO ANN M. UCHIDA
COMPLAINTS AND
ENFORCEMENT OFFICER

STATE OF HAWAII
REGULATED INDUSTRIES COMPLAINTS OFFICE
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
LEIOPAPA A KAMEHAMEHA BUILDING
235 SOUTH BERETANIA STREET, NINTH FLOOR
HONOLULU, HAWAII 96813
FAX: (808) 586-2670
TELEPHONE: (808) 586-2660

HILO OFFICE
345 KEKUANAOA STREET, SUITE 12
HILO, HAWAII 96720

KONA OFFICE
KEAUHOU SHOPPING CENTER, ROOM
134A
78-6831 ALII DRIVE
KAILUA-KONA, HAWAII 96740

MAUI OFFICE
1063 LOWER MAIN STREET, SUITE C-216
WAILUKU, HAWAII 96793

KAUAI OFFICE
3060 EIWA STREET, ROOM 204
LIHUE, HAWAII 96766

July 8, 2008

Ms. Dianna J. Wolfe
Regulatory Affairs Specialist
Medline Industries, Inc.
One Medline Place
Mundelein, Illinois 60060

Re: RICO Case No. PHA 2008-71-L

Dear Ms. Wolfe:

I received the signed Settlement Agreement. One correction had to be made, and I apologize that we did not notice this earlier. On page 3, paragraph 5, the citation to HRS section 436B-19(13) was changed to HRS section 436B-19(15) which is the correct citation. Enclosed is a copy of the corrected replacement page. I will now forward the document to the executive officer of the Board of Pharmacy, and we will be notified as to whether it gets approved or not by the Board.

Very truly yours,

Bobbi Lum-Mew

Bobbi W.Y. Lum-Mew
Staff Attorney

/BLM
Enclosure

Attachment 6b.

DARIA A. LOY-GOTO 6175
BOBBI W.Y. LUM-MEW 6299
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorney for Department of Commerce
and Consumer Affairs

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Wholesale Prescription Drug Distributor's License of	)	PHA 2008-17-L
MEDLINE INDUSTRIES INC.,	)	SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHBITS "1" THROUGH "5"
Respondent.	)	

241092407

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorneys, and Respondent MEDLINE INDUSTRIES INC. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS

1. At all relevant times herein, Respondent was licensed by the Board of Pharmacy (hereinafter the "Board") as a wholesale prescription drug distributor under License Number

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

PWD 115. The license was issued on or about October 3, 2005. The license will expire on or about December 31, 2009.

2. Respondent's mailing address for purposes of this action is One Medline Place, Mundelein, Illinois 60060.

3. RICO received information that disciplinary action had been taken against Respondent's licenses by the States of Missouri and Florida. Specifically, RICO received information regarding the following:

a). Respondent entered into a Settlement Agreement with the Missouri State Board of Pharmacy. Pursuant to the terms of a Joint Agreed Disciplinary Order, Respondent's Missouri drug distributor's license was placed on probation and Respondent was ordered to comply with certain terms and conditions. A true and correct copy of the Settlement Agreement and Joint Agreed Disciplinary Order dated July 19, 2005 in Settlement Agreement Between State Board of Pharmacy and Medline Industries, Inc., is attached as Exhibit "1";

b). Respondent was issued a Letter of Warning and Notice of Serious Violations by the Missouri State Board of Pharmacy. A true and correct copy of the Letter of Warning and Notice of Serious Violations dated February 15, 2007 regarding Medline Industries, Inc., is attached as Exhibit "2";

c). Respondent was issued an Order of Emergency Suspension of Permit by the State of Florida's Department of Health. Pursuant to the terms of the Order, Respondent's Florida prescription drug wholesaler's permit was immediately suspended . A true and correct copy of the Order of Emergency Suspension of Permit by the State of Florida's Department of Health dated January 14, 2008 in In Re: Emergency Suspension of the Permit of Medline Industries, Inc., is attached as Exhibit "3";

d). Respondent was issued an Order of Emergency Restriction of Permit by the State of Florida's Department of Health. Pursuant to the terms of the Order, Respondent's Florida prescription drug wholesaler's permit was immediately restricted. A true and correct copy of the Order of Emergency Restriction of Permit by the State of Florida's Department of Health dated January 22, 2008 in In Re: Emergency Restriction of the Permit of Medline Industries, Inc., is attached as Exhibit "4";

e). Respondent entered into a Settlement Agreement with the State of Florida's Department of Health. Pursuant to the terms of a Final Order, Respondent was, among other things, ordered to undergo quarterly inspections and pay a $50,000.00 fine. A true and correct copy of the Settlement Agreement for Final Order dated February 8, 2008 in Settlement Agreement for Final Order regarding Medline Industries, Inc., is attached as Exhibit "5."

4. RICO alleges that although Respondent reported the actions on a December 5, 2007 renewal application, Respondent failed to report the disciplinary actions within thirty (30) days as required by Hawaii law.

5. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(15) (failure to report disciplinary action within thirty days) and § 436B-19(17) (violating applicable laws or rules).

6. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein licensed as a wholesale prescription drug distributor by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the license and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's license.

6. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

7. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2008-17-L.

C. TERMS OF SETTLEMENT:

1. Probation. Respondent's wholesale prescription drug distributor's license is hereby placed on probation for a period of five (5) years. During the probationary period, Respondent agrees to comply with the following terms of the probation as set forth in paragraphs C.2, C.3, and C.4 below:

2. Comply with Terms of Missouri Probation. Respondent shall comply with the terms of its probation in the July 19, 2005 Settlement Agreement Between State Board of Pharmacy and Medline Industries, Inc.. During the probationary period, Respondent shall report to the Hawaii Board of Pharmacy, in writing, any additional action by the State of Missouri within ten (10) days of such action. During the probationary period, Respondent shall deliver to the Hawaii Board proof of Respondent's compliance with the Missouri Settlement Agreement.

3. Comply with Terms of Florida Final Order. Respondent shall comply with the terms of the February 8, 2008 Settlement Agreement for Final Order. During the probationary period, Respondent shall report to the Hawaii Board of Pharmacy, in writing, any additional action by the State of Florida within ten (10) days of such action. During the probationary period, Respondent shall deliver to the Hawaii Board proof of Respondent's compliance with the Florida Settlement Agreement.

4. Administrative fine. Respondent agrees to pay a fine in the amount of FIVE THOUSAND AND NO/100 DOLLARS ($5,000.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: Bobbi Lum-Mew, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this fully executed Settlement Agreement is returned to RICO.

5. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1, C.2, C.3 and C.4 above, Respondent's license shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the license to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new license until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become licensed again, Respondent must apply to the Board for a new license pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

6. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of wholesale prescription drug distributors in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

7. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.8, C.9, C.10 and C.11 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

8. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

9. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

10. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any

representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

11. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: _____, _____, _____.

MEDLINE INDUSTRIES INC.

By: _____
Its _____

DATED: Honolulu, Hawaii, JUL 08 2008.

Bobbi W.Y. Lum-Mew
DARIA A. LOY-GOTO
BOBBI W.Y. LUM-MEW
Attorneys for Department of Commerce and Consumer Affairs

IN THE MATTER OF THE WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR'S LICENSE OF MEDLINE INDUSTRIES INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; PHA 2008-17-L; EXHBITS "1" THROUGH "5"

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

ELWIN D.H. GOO
Chairperson

DATE

MARK E. BROWN
Vice-Chairperson

LAURIE H. Y. KAWAMURA

KENT KIKUCHI

KARL H. MIYAMOTO

PATRICK ADAMS

STANLEY M. CHOW

PVL 09/05/07

STATE OF Illinois)
) SS.
COUNTY OF Lake)

On this 3 day of July, 2007, before me personally appeared Lisa Simms, to me known to be the person described, and who executed the foregoing instrument on behalf of Medline Industries as Corporate VP of C+I/CT, and acknowledged that he/she executed the same as his/her free act and deed.

OFFICIAL SEAL
SUSAN MILLER
Notary Public - State of Illinois
My Commission Expires Jul 16, 2011

Name:
Notary Public, State of

My Commission expires: 7-16-2011

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	9/06/2008	FL	Multiple	Multiple

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
See Below	Florida Department of Health

Reason/Charge
Pedigree, Incorrect Permit, Distribution to Unauthorized Receipt, Storage

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
FL DOH / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.; Medline Manufacturing & Services, LLC

Provide explanation below:

Medline Industries Inc. and Medline Manufacturing & Services, LLC was cited for several violations related to distribution centers in Florida, including, failure to pass and maintain a Florida compliant pedigree, maintaining the wrong permit type for the activities performed (Florida required a repackager permit in addition to the existing manufacturer permit), distribution of saline to an unauthorized recipient, and storage of a prescription drug in an unlicensed raw materials storage facility. Medline challenged several violations, resulting in most being substantially reduced or removed. All issues were addressed and resolved to the satisfaction of the FL DOH. A settlement agreement was reached to resolve all matters and approved on 09/06/2008.

Corrective Actions
Medline instituted a Florida specific pedigree system to address the pedigree issues. The updated pedigree ensures that all applicable shipments to Florida have the required Florida documentation and comply with FL pedigree requirements (Note - these requirements have since been preempted by the federal Drug Supply Chain Security Act). Medline secured the repackaging permit to address the missing permit type. Medline instituted a new procedure for obtaining and maintaining customer licenses for all prescription drug purchases- this procedure generates an automatic block for any prescription drug order by an unlicensed customer. The prescription drug item unintentionally stored in the raw materials facility was properly disposed of and waste disposal procedures updated to prevent this from occurring in the future.

Locations:
10601 Southport Dr., Orlando, FL 32824
401 Commerce Blvd, Oldsmar, FL 34677
4750 118th Ave N, Clearwater, FL 33762

Case #: 2007-11783; 2007-36555; 2007-38894; 2007-38895; 2007-38896; 2007-39073; 2008-02011; 2008-11215

Original Signature (electronic, copies or stamps not accepted)

07/30/20
Date

Attachment 5.

Final Order No. DOH-08-2129-S-MQA
FILED DATE - 9-29-08
Department of Health
By: [signature]
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH.

Petitioner,

Case No.: 2007-11783; 2007-36555; 2007-38894; 2007-38895; 2007-38896; 2007-39073; 2008-02011; 2008-11215

vs.

MEDLINE, INDUSTRIES, INC.,

Respondent.
_____/

FINAL ORDER

A Notice of Violation letter was sent to the Respondent by the Department on May 14, 2008. Having received an Offer of Settlement, which is attached hereto as Exhibit A, this matter is before the Department of Health for the entry of a final order.

The Offer of Settlement was executed on or about September 19, 2008 and submitted together with the payment.

The Offer of Settlement is accepted and incorporated by reference. The parties are directed to comply with the terms of the Agreement.

It is, therefore, ORDERED that this matter and proceeding be CLOSED.

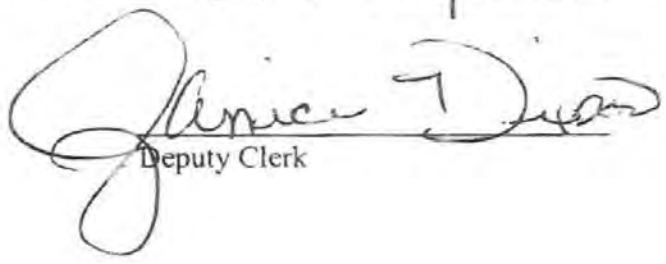
DONE and **ORDERED** this 26 day of September 2008, in Tallahassee, Leon County, Florida.

ANA M. VIAMONTE ROS. M.D., M.P.H.
State Surgeon General

By: Rebecca R. Poston
Rebecca R. Poston, R.Ph.
Executive Director
Drugs, Devices and Cosmetics

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been furnished via U.S. mail to: **Edwin Bayo, Esq., Attorney for MEDLINE INDUSTRIES, INC., at Metzger, Grossman, Furlow & Bayo, L.L.C., 1408 North Piedmont Way, Tallahassee, Florida 32308**, this 29 day of September, 2008.



Deputy Clerk

cc: Lynne Quimby-Pennock, DOH 4052 Bald Cypress Way, Bin #C-65 Tallahassee, FL 32399
Richard Sands, DOH 4052 Bald Cypress Way, Bin #C-70

SETTLEMENT AGREEMENT

Medline Industries, Inc., Case No.: 2007-11783, Permit No.: 22:596; Case No.: 2007-36555, Permit No.: No valid permit since 12.21.2006; Case No. 2007-38894, Permit No. 20:168; Case No. 2007-38895, Permit No.: 21:166; Case No. 2007-38896, Permit No.: 07:545; Case No.: 2007-39073, Permit No.: None; Case No. 2008-02011, Permit No.: None; Case No. 2008-11215, Medline Manufacturing & Services, LLC Permit No.: None

Pursuant to Section 120.57(4), Florida Statutes (2007), the above named parties hereby enter into this global stipulation as disposition of the attached administrative action, in lieu of any other administrative proceedings authorized in Chapter 120, Florida Statutes. The terms herein become effective upon rendition of the final order which shall incorporate the Settlement Agreement.

STIPULATED FACTS

1) Medline Industries Inc., and Medline Manufacturing & Services, LLC, (hereinafter collectively known as "Medline") neither admit nor deny the alleged violations in the attached Notice of Violation.
2) During the time the alleged violations occurred, Medline held certain Florida permits including: Permit No.: 22:596, a prescription drug wholesaler; Permit No.:20:168, a prescription drug manufacturer; Permit No.: 21:166 an Over the Counter Manufacturer; and Permit No.: 07:545 a device manufacturer within the state of Florida; however Medline is alleged to have failed to have certain other permits in the Notice of Violation.
3) The Department is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 20.43, Florida Statutes (2007), and Chapter 499, Florida Statutes (2007).

EXHIBIT

0265

CONCLUSIONS OF LAW

4) Medline, by and through its undersigned agent, admits that it is subject to the provisions of Chapter 499, Florida Statutes (2007), and the jurisdiction of the Department.

5) Medline admits that the findings set forth in the Notice of Violation, if proven, would constitute violations of Chapter 499, Florida Statutes (2007).

6) Medline agrees that the Department's acceptance of the Settlement Agreement constitutes disciplinary action within the meaning of Section 499.066, Florida Statutes (2007), and Rule 64F-12.024, Florida Administrative Code.

SETTLEMENT

7) Medline agrees to pay a fine of ONE HUNDRED FIFTY THOUSAND DOLLARS ($150,000.00), and acknowledges that payment, made payable to the Florida Drug, Device and Cosmetic Trust Fund, is enclosed with this agreement.

8.) Medline affirms the violations cited the Notice of Violation letter issued under these case numbers have been corrected or are being corrected immediately. Medline shall provide written documentation of the return of the seized products to a licensed reverse distributor within thirty (30) days of the execution of this agreement. The documentation shall be sent to the Florida Drug Device and Cosmetic Program Office, Department of Health, 4052 Bald Cypress Way, Bin C04, Tallahassee, FL 32399-3255. Upon receipt of documentation demonstrating the return of the seized products, the seizure order shall automatically be lifted.

9) Medline affirms that it shall comply with all provisions of the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes, and the rules adopted thereunder.

10) It is expressly understood that a violation of the terms of this Settlement Agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary actions may be taken.

11) Medline expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Settlement Agreement incorporated in the Final Order.

12) Medline waives the right to seek any attorney's fees or costs from the Department in connection with this disciplinary proceeding.

Corporate Seal:

By: _____ 9/19/08
President (or authorized agent) Date

Attested by: _____ _____
Corporate Secretary Date

By: Rebecca R Poston 9/26/08
Authorized DOH Representative Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	02/04/2009	WI	Wausau	Marathon

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
08 PHM 037	Wisconsin Department of Regulation and Licensing

Reason/Charge
Failure to Separate Products, Failure to retrieve Policies and Procedure during Inspection

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
WI DSPS/ Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries Inc. distribution center at 5450 W. Stewart Ave., Wausau, WI 54401 (WI # 1116-045) cited for missing policies and procedures and storage of drugs in a non-secure location following an inspection by the Wisconsin Department of Regulation & Licensing. Medline managed a portion of a Wisconsin hospital's warehouse. The inspector cited Medline for failure to install a dividing fence between the Medline warehouse and the hospital portion of the facility. All hospital products were owned by the hospital. Medline was also cited for failure to access policies and procedures during the inspection. Corrections were made and the facility re-inspected, to the satisfaction of the state. Medline entered a stipulation order effective 02/04/2009 to resolve the matter.

Corrective Actions:
Medline installed a locked fence to separate the hospital's owned products. Medline also completed a review of all facilities to ensure proper separation of products. On-site staff provided additional training on how to access current policies and procedures during an inspection.

Original Signature (electronic, copies or stamps not accepted)

01/30/26
Date

Jim Doyle
Governor

Celia M. Jackson
Secretary

WISCONSIN DEPARTMENT OF REGULATION & LICENSING

1400 E Washington Ave
PO Box 8935
Madison WI 53708-8935
Email: web@drl.state.wi.us
Voice: 608-266-2112
FAX: 608-266-2264
TTY: 608-267-2416

November 18, 2008

Jan Hornick
Medline Industries Inc.
5450 W. Stewart Ave.
Wausau, WI 54401

Re: 08 PHM 037

Dear Ms. Hornick:

As you know, an inspector for the Department of Regulation and Licensing inspected Medline Industries on May 9, 2008. He found that several policies were missing, and the facility was storing prescription drugs in a non-secure location. It has been determined that these violations are grounds for discipline. I am the prosecuting attorney assigned to the case.

I have enclosed a proposed stipulation and order, which would resolve this matter without a hearing. If you are willing to resolve this case by agreement, please sign and return the stipulation and order **by December 9, 2008**. I will then present it to the Pharmacy Examining Board at its next meeting. The stipulation and order is not binding unless and until it is accepted by the board.

If you do not return the signed stipulation and order by December 9, 2008, I will file a formal complaint and initiate the hearing process. Please be aware that it is the policy of the Department to assess costs against respondents whenever any discipline is imposed. Your costs are presently $100. If we have to take this matter through a hearing, they will escalate quickly and could reach several thousand dollars.

Please call if you have any questions.

Sincerely,

Jeanette Lytle
Attorney
Division of Enforcement
608-266-9840

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	STIPULATION
MEDLINE INDUSTRIES INC.	:	LS# _____
RESPONDENT.	:	

Division of Enforcement Case # 08 PHM 037

Respondent Medline Industries Inc., by its manager Jan Hornick; and Jeanette Lytle, attorney for the Department of Regulation and Licensing, Division of Enforcement, stipulate:

1. This Stipulation is entered into as a result of a pending investigation of Respondent's licensure by the Division of Enforcement (case # 08 PHM 037). Jan Hornick represents, by her signature below, that she has authority to enter into this agreement on behalf of Respondent. Ms. Hornick, on behalf of Respondent, consents to the resolution of this investigation by stipulation.

2. Respondent's manager, Jan Hornick, understands that by signing this Stipulation she voluntarily and knowingly waives on behalf of Respondent its rights, including: the right to a hearing on the allegations against it, at which time the state has the burden of proving those allegations by a preponderance of the evidence; the right to confront and cross-examine witnesses; the right to call witnesses and to compel their attendance by subpoena; the right to testify; the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision; the right to petition for rehearing; and all other applicable rights afforded to it under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and any other provisions of state or federal law.

3. Respondent has been provided an opportunity to obtain the advice of legal counsel prior to signing this stipulation.

4. Jan Hornick agrees, on behalf of Respondent, to the adoption of the attached Final Decision and Order by the Pharmacy Examining Board. The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall be returned to the Division of Enforcement for further proceedings. In the event that this Stipulation is

not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by consideration of this attempted resolution.

6. The parties to this Stipulation agree that the attorney or other agent for the Division of Enforcement and any member of the Pharmacy Examining Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of the Respondent or its attorney, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with the Board's deliberations on the Stipulation. Additionally, any such Board advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's final decision and order is a public record and will be published in accordance with standard Department procedure.

8. The Division of Enforcement joins Jan Hornick in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.

Medline Industries Inc.

By: Jan Hornick
Jan Hornick, manager
5450 West Stewart Avenue
Wausau, WI 54401

11-24-08
Date

Jeanette Lytle
Attorney
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935
Madison, WI 53708-8935

Date

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
MEDLINE INDUSTRIES INC., RESPONDENT.	:	LS # _____

Division of Enforcement Case # 08 PHM 037

The parties to this action for the purposes of Wis. Stat. § 227.53 are:

Medline Industries Inc.
5450 W. Stewart Ave.
Wausau, WI 54401

Division of Enforcement
Department of Regulation and Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

Pharmacy Examining Board
Department of Regulation & Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

PROCEDURAL HISTORY

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Pharmacy Examining Board. The Board has reviewed the attached Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. Medline Industries Inc. is duly licensed as a wholesale distributor of prescription drugs in Wisconsin (license # 45-1116). This license was first granted on June 21, 1999.

2. Respondent's most recent address on file with the Wisconsin Pharmacy Examining Board is 5450 W. Stewart Avenue, Wausau, Wisconsin 54401.

3. The Department of Regulation and Licensing conducted an unannounced inspection on May 9, 2008. The following violations were noted:

(a) The following policies were missing: Recall policy [Wis. Admin. Code § Phar 13.15(2)], Emergency plan [Wis. Admin. Code § Phar 13.15(3)], Outdated stock policy [Wis. Admin. Code § Phar 13.15(4).

(b) Respondent was storing Complete Delivery Systems (pre-packaged kits for surgeries, including various types and quantities of prescription drugs) in a warehouse it shared with another company. The CDS kits were not secured and employees of the other company had unhindered access to the kits, in violation of Wis. Admin. Code § Phar 13.10(3).

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter, pursuant to Wis. Stat. §450.10, and is authorized to enter into the attached Stipulation and Order, pursuant to Wis. Stat. § 227.44(5).

2. The conduct described in paragraph 3 above constitutes a violation of Wisconsin Administrative Code § Phar 13.10(3), Phar 13.15(2), (3) and (4), and Wis. Stat. § 450.10(1)(a)2 and 6 and subjects Respondent to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

ORDER

IT IS ORDERED:

1. Medline Industries Inc. is REPRIMANDED.

2. Respondent shall, within ninety (90) days from the date of this Order, pay a FORFEITURE in the amount of Two Thousand Dollars ($2,000.00).

3. Respondent shall, within ninety (90) days from the date of this Order, pay costs of this proceeding in the amount of One Hundred Dollars ($ 100.00). Payment shall be made payable to the Wisconsin Department of Regulation and Licensing, and mailed to:

Department Monitor
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935

Madison, WI 53708-8935
Telephone (608) 267-3817
Fax (608) 266-2264

4. In the event Respondent fails to pay the forfeiture as ordered, or in the event it fails to pay costs as ordered, Respondent's license (#45-1116) SHALL BE SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of this Order.

5. This Order is effective on the date of its signing.

Dated this __ day of _____, 2008.

PHARMACY EXAMINING BOARD

By: _____
A Member of the Board

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
MEDLINE INDUSTRIES INC., RESPONDENT.	:	LS # 0902046PHM

Division of Enforcement Case # 08 PHM 037

The parties to this action for the purposes of Wis. Stat. § 227.53 are:

Medline Industries Inc.
5450 W. Stewart Ave.
Wausau, WI 54401

Division of Enforcement
Department of Regulation and Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

Pharmacy Examining Board
Department of Regulation & Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

PROCEDURAL HISTORY

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Pharmacy Examining Board. The Board has reviewed the attached Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. Medline Industries Inc. is duly licensed as a wholesale distributor of prescription drugs in Wisconsin (license # 45-1116). This license was first granted on June 21, 1999.

2. Respondent's most recent address on file with the Wisconsin Pharmacy Examining Board is 5450 W. Stewart Avenue, Wausau, Wisconsin 54401.

3. The Department of Regulation and Licensing conducted an unannounced inspection on May 9, 2008. The following violations were noted:

(a) The following policies were missing: Recall policy [Wis. Admin. Code § Phar 13.15(2)], Emergency plan [Wis. Admin. Code § Phar 13.15(3)], Outdated stock policy [Wis. Admin. Code § Phar 13.15(4).

(b) Respondent was storing Complete Delivery Systems (pre-packaged kits for surgeries, including various types and quantities of prescription drugs) in a warehouse it shared with another company. The CDS kits were not secured and employees of the other company had unhindered access to the kits, in violation of Wis. Admin. Code § Phar 13.10(3).

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter, pursuant to Wis. Stat. §450.10, and is authorized to enter into the attached Stipulation and Order, pursuant to Wis. Stat. § 227.44(5).

2. The conduct described in paragraph 3 above constitutes a violation of Wisconsin Administrative Code § Phar 13.10(3), Phar 13.15(2), (3) and (4), and Wis. Stat. § 450.10(1)(a)2 and 6 and subjects Respondent to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

ORDER

IT IS ORDERED:

1. Medline Industries Inc. is REPRIMANDED.

2. Respondent shall, within ninety (90) days from the date of this Order, pay a FORFEITURE in the amount of Two Thousand Dollars ($2,000.00).

3. Respondent shall, within ninety (90) days from the date of this Order, pay costs of this proceeding in the amount of One Hundred Dollars ($ 100.00). Payment shall be made payable to the Wisconsin Department of Regulation and Licensing, and mailed to:

Department Monitor
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935

Madison, WI 53708-8935
Telephone (608) 267-3817
Fax (608) 266-2264

4. In the event Respondent fails to pay the forfeiture as ordered, or in the event it fails to pay costs as ordered, Respondent's license (#45-1116) SHALL BE SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of this Order.

5. This Order is effective on the date of its signing.

Dated this 4 day of February, 2009.

PHARMACY EXAMINING BOARD

By: _____
A Member of the Board

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	05/19/2009	HI	Waipahu	Honolulu

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
PHA 2009-7-L	Hawaii Department of Commerce and Consumer Affairs

Reason/Charge
Discipline incurred in another jurisdiction

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
HI DCCA / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. agreed to enter a Consent Order for discipline incurred in another jurisdiction (Wisconsin Case #: 08 PHM 037).

Original Signature (electronic, copies or stamps not accepted)

07/30/12

Date

BOBBI W.Y. LUM-MEW 6299
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorney for Department of Commerce
and Consumer Affairs

2009 MAY 22 A 9:24 2009 MAY 19 A 9:4

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Wholesale Prescription Drug Distributor's License of MEDLINE INDUSTRIES INC., Respondent.	PHA 2009-7-L SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"

241092407

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorneys, and Respondent MEDLINE INDUSTRIES INC. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS

1. At all relevant times herein, Respondent was licensed by the Board of Pharmacy (hereinafter the "Board") as a wholesale prescription drug distributor under License Number PWD 115. The license was issued on or about October 3, 2005. The license will expire on or about December 31, 2009.

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

2. Respondent's mailing address for purposes of this action is Dianna Wolfe, Corporate Regulatory Affairs Specialist, Medline Industries, Inc., One Medline Place, Mundelein, Illinois 60060.

3. Respondent timely reported that disciplinary action had been taken against Respondent by the State of Wisconsin. Respondent had entered into a Stipulation with the State of Wisconsin's Pharmacy Examining Board. Pursuant to the terms of a Final Order, Respondent was reprimanded and ordered to pay a forfeiture in the amount of $2,000.00. This action was based on the results of an inspection which revealed that certain policies were missing and that Respondent was storing pre-packaged kits for surgeries (which included various types and quantities of prescription drugs) in a warehouse that was shared with another company. These kits were not secured and employees of the other company had access to the kits. A true and correct copy of the Stipulation and Final Decision and Order which was approved on February 4, 2009 is attached as Exhibit "1."

4. RICO alleges that Respondent was disciplined by another state for a reason provided by the licensing laws in Hawaii. Specifically, the Respondent was disciplined for professional misconduct.

5. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(13) (disciplinary action by another state) and § 461-21(a)(2) (professional misconduct). Per Hawaii Administrative Rules §§ 16-95-30(c)(6) and (9), a licensee's facility must be secure from unauthorized entry and entry into areas where prescription drugs are held must be limited to authorized personnel.

6. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein licensed as a wholesale prescription drug distributor by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the license and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's license.

6. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

7. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2009-7-L.

C. TERMS OF SETTLEMENT:

1. Administrative fine. Respondent agrees to pay a fine in the amount of ONE THOUSAND AND NO/100 DOLLARS ($1,000.00). Payment shall be made by **cashier's check, company check, or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: Bobbi Lum-Mew, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due within thirty (30) days after this Settlement Agreement is approved by the Board.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph C.1 above, Respondent's license shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the license to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new license until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become licensed again, Respondent must apply to the Board for a new license pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of wholesale prescription drug distributors in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5, C.6, C.7 and C.8 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: Mundelein (CITY), IL (STATE), 5/11/09 (DATE).

MEDLINE INDUSTRIES INC.

By: [signature]
Its Pres. of GAIRA

DATED: Honolulu, Hawaii, MAY 19 2009.

[signature]
DARIA A. LOY-GOTO
BOBBI W.Y. LUM-MEW
Attorneys for Department of Commerce and Consumer Affairs

IN THE MATTER OF THE WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR'S LICENSE OF MEDLINE INDUSTRIES INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; PHA 2009-7-L; EXHIBIT "1"

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

ELWIN D.H. GOO
Chairperson

June 18, 2009
DATE

MARK E. BROWN
Vice-Chairperson

LAURIE H. Y. KAWAMURA

KENT KIKUCHI

KARL H. MIYAMOTO

PATRICK ADAMS

STANLEY M. CHOW

PVL 05/20/08

STATE OF Illinois)
) SS.
COUNTY OF Lake)

On this 11 day of May, 2009, before me personally appeared Lacy V Simms, to me known to be the person described, and who executed the foregoing instrument on behalf of Mallie Industries as President, CEO/CFO, and acknowledged that he/she executed the same as his/her free act and deed.

OFFICIAL SEAL
SUSAN MILLER
Notary Public - State of Illinois
My Commission Expires Jul 16, 2011

Name: Susan Miller
Notary Public, State of IL

My Commission expires: July 16, 2011

2009

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
MEDLINE INDUSTRIES INC., RESPONDENT.	:	LS # 0902046PHM

Division of Enforcement Case # 08 PHM 037

The parties to this action for the purposes of Wis. Stat. § 227.53 are:

Medline Industries Inc.
5450 W. Stewart Ave.
Wausau, WI 54401

Division of Enforcement
Department of Regulation and Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

Pharmacy Examining Board
Department of Regulation & Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

PROCEDURAL HISTORY

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Pharmacy Examining Board. The Board has reviewed the attached Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. Medline Industries Inc. is duly licensed as a wholesale distributor of prescription drugs in Wisconsin (license # 45-1116). This license was first granted on June 21, 1999.

EXHIBIT "1"

2. Respondent's most recent address on file with the Wisconsin Pharmacy Examining Board is 5450 W. Stewart Avenue, Wausau, Wisconsin 54401.

3. The Department of Regulation and Licensing conducted an unannounced inspection on May 9, 2008. The following violations were noted:

(a) The following policies were missing: Recall policy [Wis. Admin. Code § Phar 13.15(2)], Emergency plan [Wis. Admin. Code § Phar 13.15(3)], Outdated stock policy [Wis. Admin. Code § Phar 13.15(4).

(b) Respondent was storing Complete Delivery Systems (pre-packaged kits for surgeries, including various types and quantities of prescription drugs) in a warehouse it shared with another company. The CDS kits were not secured and employees of the other company had unhindered access to the kits, in violation of Wis. Admin. Code § Phar 13.10(3).

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter, pursuant to Wis. Stat. §450.10, and is authorized to enter into the attached Stipulation and Order, pursuant to Wis. Stat. § 227.44(5).

2. The conduct described in paragraph 3 above constitutes a violation of Wisconsin Administrative Code § Phar 13.10(3), Phar 13.15(2), (3) and (4), and Wis. Stat. § 450.10(1)(a)2 and 6 and subjects Respondent to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

ORDER

IT IS ORDERED:

1. Medline Industries Inc. is REPRIMANDED.

2. Respondent shall, within ninety (90) days from the date of this Order, pay a FORFEITURE in the amount of Two Thousand Dollars ($2,000.00).

3. Respondent shall, within ninety (90) days from the date of this Order, pay costs of this proceeding in the amount of One Hundred Dollars ($ 100.00). Payment shall be made payable to the Wisconsin Department of Regulation and Licensing, and mailed to:

Department Monitor
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935

Madison, WI 53708-8935
Telephone (608) 267-3817
Fax (608) 266-2264

4. In the event Respondent fails to pay the forfeiture as ordered, or in the event it fails to pay costs as ordered, Respondent's license (#45-1116) SHALL BE SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of this Order.

5. This Order is effective on the date of its signing.

Dated this 4 day of February, 2009.

PHARMACY EXAMINING BOARD

By: Gregory C. Lisby
A Member of the Board

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF :
DISCIPLINARY PROCEEDINGS AGAINST :
:
MEDLINE INDUSTRIES INC. :
RESPONDENT. :

STIPULATION
LS#0902046PHM

Division of Enforcement Case # 08 PHM 037

Respondent Medline Industries Inc., by its manager Jan Hornick; and Jeanette Lytle, attorney for the Department of Regulation and Licensing, Division of Enforcement, stipulate:

1. This Stipulation is entered into as a result of a pending investigation of Respondent's licensure by the Division of Enforcement (case # 08 PHM 037). Jan Hornick represents, by her signature below, that she has authority to enter into this agreement on behalf of Respondent. Ms. Hornick, on behalf of Respondent, consents to the resolution of this investigation by stipulation.

2. Respondent's manager, Jan Hornick, understands that by signing this Stipulation she voluntarily and knowingly waives on behalf of Respondent its rights, including: the right to a hearing on the allegations against it, at which time the state has the burden of proving those allegations by a preponderance of the evidence; the right to confront and cross-examine witnesses; the right to call witnesses and to compel their attendance by subpoena; the right to testify; the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision; the right to petition for rehearing; and all other applicable rights afforded to it under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and any other provisions of state or federal law.

3. Respondent has been provided an opportunity to obtain the advice of legal counsel prior to signing this stipulation.

4. Jan Hornick agrees, on behalf of Respondent, to the adoption of the attached Final Decision and Order by the Pharmacy Examining Board. The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall be returned to the Division of Enforcement for further proceedings. In the event that this Stipulation is

not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by consideration of this attempted resolution.

6. The parties to this Stipulation agree that the attorney or other agent for the Division of Enforcement and any member of the Pharmacy Examining Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of the Respondent or its attorney, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with the Board's deliberations on the Stipulation. Additionally, any such Board advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's final decision and order is a public record and will be published in accordance with standard Department procedure.

8. The Division of Enforcement joins Jan Hornick in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.

Medline Industries Inc.

By: Jan Hornick 11-24-08

Jan Hornick, manager
5450 West Stewart Avenue
Wausau, WI 54401

Date

12/10/08

Jeanette Lytle
Attorney
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935
Madison, WI 53708-8935

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	03/19/2010	MO	Kansas City	Jackson

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2010-002994	Colorado State Board of Pharmacy

Reason/Charge
Conditional License

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
CO Board of Pharmacy / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. distribution center at 1401 N. Universal Ave, Kansas City, MO 64120 applied for a Colorado Out-of-State Wholesaler license. The CO Board of Pharmacy issued a conditional license until the facility's MO probation period ended. (See Case 2003031660 above). Medline informed the CO Board when the MO probationary period was completed. Upon completion of probation, the Board issued a full license.

Corrective Actions:
Medline successfully completed terms of probation in MO and CO.

Original Signature (electronic, copies or stamps not accepted)

01/30/26
Date

Dora
Department of Regulatory Agencies

Division of Registrations
Rosemary McCool
Director

State Board of Pharmacy
Wendy Anderson
Program Director

Bill Ritter, Jr.
Governor

Barbara J. Kelley
Executive
Director

March 24, 2010

MedLine Industries, Inc.
Attn: Scott C. Barbour, Designated Representative
1401 N. Universal Ave.
Kansas City, MO 64120

RE: Stipulation and Final Agency Order
Case #2010-2994

IN THE MATTER OF DISCIPLINARY RPOCEEDINS REGARDING THE LICENSE TO PRACTICE AS A OUT-OF-STATE WHOLESALER IN THE STATE OF COLORADO OF MEDLINE INDUSTRIES, INC.,

Dear Mr. Barbour:

Enclosed you will find a copy of the fully executed Stipulation and Final Agency Order (Stip/FAO) in the above mentioned matter, which became effective March 19, 2010.

Accordingly, and pursuant to Conditional Registration, item 9, of the Stip/FAO, MedLine Industries, Inc., at the above listed location, has been issuec out-of-state prescription drug wholesaler registration #7713, with conditions, effective March 23, 2010.

Medline Industries, Inc., Colorado out-of-state wholesaler registration #7713 shall be probationary pending the Colorado State Board of Pharmacy's receipt of a request for discharge from Medline Industries, Inc., which must include documentation showing Medline Industries, Inc.'s release from the terms and conditions of the Missouri Settlement Agreement effective 8/3/05.

If you have any questions, or require additional information, please feel free to contact me at (303) 894-2989.

Respectfully,

FOR THE COLORADO STATE BOARD OF PHARMACY

Tia Johnson
Complaint Analyst
Enclosure
cc: Beth Thompson, Vice President, Regulatory Affairs, Medline Industries, Inc.
John Steele, Settlement Specialist, Office of Expedited Settlement
Jazell Carter, Licensing Specialist, Office of Licensing
File

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2010-002994

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE LICENSE TO PRACTICE AS A OUT-OF-STATE WHOLESALER IN THE STATE OF COLORADO OF MEDLINE INDUSTRIES, INC.,

Wholesaler Applicant.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Medline Industries, Inc. ("Wholesaler Applicant") to resolve all matters pertaining to Board Case Number 2010-002994 as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Wholesaler Applicant, its application for registration as an out-of-state wholesaler and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S.

2. Wholesaler Applicant admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

3. Wholesaler Applicant entered into a Settlement Agreement with the Missouri State Board of Pharmacy, which was effective on August 3, 2005 ("Missouri Settlement Agreement").

4. In the Missouri Settlement Agreement, Wholesaler Applicant was placed on probation for five (5) years for various violations of Missouri state and federal law involving recordkeeping, storage of prescription drugs, change of location without informing the Missouri Board of Pharmacy, lack of a policy and procedure manual, and distribution of prescription drugs under a lapsed registration.

5. Wholesaler Applicant's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes:

12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(III) Any state or federal law pertaining to drugs.

12-22-125.2. Disciplinary actions.

(1) The board may deny or discipline an applicant, licensee, or registrant when the board determines that such applicant, licensee, or registrant has engaged in activities that are grounds for discipline.

6. On January 14, 2010, Wholesaler Applicant submitted an out-of-state wholesaler application, which application was denied by the Board.

7. On March 1, 2010, Wholesaler Applicant submitted a written request asking that the Board accept its application by granting a conditional license.

8. The Board finds and concludes, and Wholesaler Applicant agrees, that based upon Wholesaler Applicant's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances as a condition of its registration as an out-of-state wholesaler.

DISPOSITION

Conditional Registration / Probation / Compliance / Terms

9. **Conditional Registration.** Wholesaler Applicant shall be granted a registration as an out-of-state wholesaler upon execution of this Final Agency Order and satisfaction of the terms and conditions set forth herein.

10. **Probation.** Wholesaler Applicant's registration shall be placed on probation for a period of time equal to the time of probation remaining under the Missouri Settlement Agreement. Credit toward satisfying the period of probation under this Final Agency Order shall be given only during such periods of time that Respondent is in total compliance with all provisions of this Final Agency Order and the Missouri Settlement Agreement.

11. **Compliance.** Wholesaler Applicant shall at all times remain in compliance with §§12-22-801, *et seq.* C.R.S. and shall not at any time distribute prescription drugs into Colorado without being registered as an out-of-state wholesaler in the State of Colorado at the time of distribution.

12. **Other Requirements.** Wholesaler Applicant acknowledges and agrees that, as a condition of this Final Agency Order and probation, Wholesaler Applicant shall:

    a. promptly pay all Wholesaler Applicant's own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

13. **Discharge.** Discharge from the requirements of this Final Agency Order must be requested in writing by Wholesaler Applicant. The Board will consider any request for discharge during the ordinary course of business. In any request for discharge it shall be Wholesaler Applicant's sole responsibility to establish, through written and other documentation, that Wholesaler Applicant has met all terms and conditions of this Final Agency Order and, in addition, has been released from probation by the Missouri Board of Pharmacy under the Missouri Settlement Agreement. Wholesaler Applicant's probation under this Final Agency Order shall continue until formally discharged by the Board by way of Board order.

14. **Advisements and Waivers.** Wholesaler Applicant enters into this Final Agency Order freely and voluntarily, whether or not Wholesaler Applicant has consulted with legal counsel. Wholesaler Applicant acknowledges its understanding that it has the following rights:

    a. To have a formal notice of hearing and charges served upon it;
    b. To respond to said formal notice of charges;
    c. To have a formal disciplinary hearing pursuant to §12-22-125, C.R.S.; and
    d. To appeal this Board order.

    Wholesaler Applicant freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

15. **Acknowledgments.** The undersigned authorized agent of Wholesaler Applicant has read this Final Agency Order in its entirety and acknowledges, whether or not Wholesaler Applicant has consulted with legal counsel, that Wholesaler Applicant

understands the legal consequences and agrees that none of the terms or conditions herein are unconscionable.

16. **Violations.** Time is of the essence to this Final Agency Order. It is the responsibility of Wholesaler Applicant to take all appropriate steps to comply fully with this Final Agency Order. Wholesaler Applicant acknowledges and agrees that any violation of this Final Agency Order may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Wholesaler Applicant to comply with all terms and conditions of this Final Agency Order.

17. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

18. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

19. **Effective Date.** This Final Agency Order shall become effective upon signature of a Board member or representative.

ACCEPTED AND AGREED BY

Dated: 3/12/10

Authorized Agent of Wholesaler Applicant

Subscribed and sworn to by Lisa N. Simmons, in his/her capacity as an authorized agent of Medline Industries, Inc., before me in the County of Lake, State of Illinois, this 12 day of March, 2010.

OFFICIAL SEAL
SUSAN MILLER
Notary Public - State of Illinois
My Commission Expires Jul 16, 2011

Notary Public

My commission expires: 7-16-2011

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 19th day of March, 2010.

State Board of Pharmacy

BY: Wendy Anderson
Wendy Anderson
Program Director

CERTIFICATE OF MAILING

This is to certify that I have duly mailed the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 5th day of March 2010, addressed as follows:

Medline Industries, Inc.
Attn: Scott C. Barbour, Designated
Representative
1401 N. Universal Ave.
Kansas City, MO 64120

Beth Thompson
Vice President, Regulatory Affairs
Medline Industries, Inc.
1 Medline Pl.
Mundelein, IL 60060

John Steele
John C. Steele

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 24th day of March 2010, addressed as follows:

Medline Industries, Inc.
Attn: Scott C. Barbour, Designated
Representative
1401 N. Universal Ave.
Kansas City, MO 64120

Beth Thompson
Vice President, Regulatory Affairs
Medline Industries, Inc.
1 Medline Pl.
Mundelein, IL 60060

Agent of the Board

Dora
Department of Regulatory Agencies

Division of Registrations
Rosemary McCool
Director

State Board of Pharmacy
Wendy Anderson
Program Director

Bill Ritter, Jr.
Governor

Barbara J. Kelley
Executive
Director

August 25, 2010

MedLine Industries, Inc.
Attn: Scott C. Barbour, Designated Representative
1401 N. Universal Ave.
Kansas City, MO 64120

RE: Stipulation and Final Agency Order (Stip/FAO), effective 3/19/10
Case #2010-2994

Dear Mr. Barbour:

Staff for the Colorado State Board of Pharmacy ("Board") has reviewed the material concerning Medline Industries' request for release from the terms and conditions of the above listed Stip/FAO effective 3/19/10.

After due consideration, and pursuant to Board Policy 10-6, staff for the Board released Medline Industries, Inc., from the terms and conditions of the 3/19/10 Stip/FAO, and restored its out-of-state prescription drug wholesaler registration #7713 to unencumbered status, effective 8/25/10.

Your cooperation during the pendency of this matter is sincerely appreciated.

Sincerely,

FOR THE COLORADO STATE BOARD OF PHARMACY

Wendy L. Anderson
Program Director

cc: Beth Thompson, Vice President, Regulatory Affairs, Medline Industries, Inc.
File

Policy Number: 10-6

Title: Delegation of Authority to Program Director or Section Director

Date Issued: 11/16/2006

Dates Revised: 8/21/08, 10/16/08, 9/17/09, 1/21/10, 7/15/2010

PURPOSE: To clarify the authority which has been delegated to the Program Director, Section Director, or his/her designee.

POLICY: The Board of Pharmacy has delegated to the Program Director, Section Director or his/her designee the authority to:

1. Sign Stipulations and Final Agency Orders ("Stipulations") and final orders issued subsequent to initial decisions entered after hearings held by administrative law judges ("Final Board Orders") on its behalf.

2. Issue Final Board Orders on its behalf when no exceptions are filed to the initial decision, the statutorily allowed time frame for the filing of exceptions has passed, the recommended sanction from the Administrative Law Judge is the same as that sought by the Board, and no further decisions are required by the Board.

3. Process reports of settlement of malpractice claims in the same manner as signed complaints are handled.

4. Accept, on the Board's behalf, practice and treatment monitoring reports and any other such reports submitted as required by the Stipulation or Final Board Order, provided such reports are in compliance with the terms of the Stipulation or Final Board Order.

5. Initiate complaints and issue 30-day letters to licensees or registrants currently under Stipulation or Final Board Order if, in the opinion of the Program Director or his/her designee, the licensee or registrant has failed to comply with any of the terms of his or her stipulation.

6. Sign Suspension Orders as required by the Child Support Enforcement Program.

7. Subpoena documents and gather information in order to assist the Board in carrying out its duties.

8. Approve practice monitors for licensees and registrants as required pursuant to Stipulations or Final Board Orders.

9. Sign suspension orders on its behalf.

10. Sign cease and desist orders on its behalf.

11. Perform the initial review of complaints relating to the practice of licensees or registrants under the Board's jurisdiction and to issue 30-day letters relating to the complaints.

12. Initiate complaints and issue 30-day letters where otherwise authorized by the Board.

13. Determine non-substantive procedural matters relating to the rendering of initial decisions, including, but not limited to, granting extensions of time for the filing of exceptions, and granting requests for oral argument.

14. Perform additional delegated duties as set forth in Board policies.

15. Make referrals for assessment to the Pharmacy Peer Assistance Diversion Program.

16. Suspend the licenses of individuals under Stipulation or Final Board Order if licensee is required to participate in the Pharmacy Peer Assistance Diversion Program as a requirement of his/her Stipulation or Final Board Order and fails to comply with his/her contract with the Rehabilitation Evaluation Committee. The Program Director or his/her designee may lift the Board suspension on such licenses when the licensee has resumed compliance.

17. Release licensees and registrants from the terms of their Stipulations or Final Board Orders provided the licensee submits satisfactory evidence of completion of all terms of the Stipulation or Final Board Order. The Program Director or his/her designee, at his/her discretion, may refer any request for discharge to the Board for review.

18. Deny requests from licensees and registrants for discharge from the terms of Stipulations or Final Board Orders when the licensee or registrant has not completed the terms of the Stipulation or Final Board Order. Requests for early discharge from Stipulations and Final Board Orders shall be denied.

19. Suspend the licenses or registrations of facilities which have been ordered to pay a fine pursuant to a Stipulation or Final Board Order and fail to remit the required payment. In the event the licensee or registrant is to pay the fine in installments, the Program Director or his/her designee may suspend the license or registration if the licensee or registrant fails to remit a required payment. The Program Director or his/her designee may lift the Board suspension on such licenses or registrations when the licensee or registrant has come into compliance with fine requirements.

20. Enter, on its behalf, written agreements with public or private entities whereby the Board may provide information from the Electronic Prescription Drug Monitoring Program that does not identify a patient, prescriber, or dispenser of a prescription drug. Such agreements may only be entered into for the purposes of bona fide research or education pursuant to CRS 12-22-705(5).

21. Notice, on its behalf, proposed rules or proposed amendments or deletions to rules for a hearing before the board pursuant to CRS 24-4-103.

22. In the absence of additional exculpatory evidence or information not previously before the board, reject any counteroffer from respondents with cases at the Office of Expedited Settlement that is not within the board's settlement parameters.

23. Issue on its behalf, the "Board Procedural Order regarding Review of Initial Decision" upon receipt of an Initial Decision from an Administrative Law Judge at the Office of Administrative Courts.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	7/18/2014	NY	Middletown	Orange

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
27278	NY State Education Department- Board of Pharmacy

Reason/Charge
Discipline incurred in another jurisdiction

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
NY Board of Pharmacy / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. agreed to enter a Consent Order for discipline incurred in another jurisdiction (FL No. 2007-37412, LA No. 2008006, and WI No. 08 PHM 037).

Corrective Actions:
See corrective actions for FL No. 2007-37412, LA No. 2008006, and WI No. 08 PHM 037.

Original Signature (electronic, copies or stamps not accepted)

07/30/26
Date

THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK

OFFICE OF PROFESSIONAL DISCIPLINE
(212) 921-3872/3873

1411 BROADWAY – TENTH FLOOR
NEW YORK, NEW YORK 10018

July 18, 2014

Medline Industries Inc., Pharmacy Wholesaler
3301 Route 6
Middletown, NY 10940

Re: License No. 028250

Dear Sir or Madam:

Enclosed please find Order No. 27278. This letter will explain when the Order regarding the above respondent goes into effect.

If the penalty imposed by the Order is an annulment, revocation, surrender, or an actual suspension (suspension which is not wholly stayed) of your license, you must deliver your license and registration to this Department within ten (10) days after the date of this letter.

In the event you are personally served with the Order, the Order is effective as of the date of the personal service. In the event you are served by certified mail and are not personally served with the Order, the Order is effective five (5) days after the date of this letter. The Order will take effect as indicated in this letter, even if you fail to meet the time requirement of delivering your license and registration to this Department.

If the penalty imposed by the Order is a revocation or a surrender of your license, you may, pursuant to Rule 24.7 (b) of the Rules of the Board of Regents, a copy of which is attached, apply for restoration of your license after three years have elapsed from the effective date of the Order and the penalty. Please be advised that said application is not granted automatically.

The record and reports of a disciplinary proceeding or resulting voluntary settlement shall be considered matters of public information unless specifically excepted by law or applicable rule or regulation.

Very truly yours,

DONALD DAWSON
Director of Investigations
By: A. Miller
ARIANA MILLER
Supervisor

LJC/AM/nbm
Enclosure
CERTIFIED MAIL – RRR
cc: Judith A. Eisen, Esq.
Garfunkel Wild, P.C.
111 Great Neck Road
Great Neck, NY 11021

C201406

VOTE AND ORDER

MEDLINE INDUSTRIES INC.

CALENDAR NO. 27278

NEW YORK STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE
STATE BOARD OF PHARMACY
----------X

IN THE MATTER

of the

Disciplinary Proceeding

against

MEDLINE INDUSTRIES INC.

which is currently registered to operate as a pharmacy wholesaler in the State of New York.
----------X

APPLICATION FOR CONSENT ORDER

CAL. NO. 27278

LARA N. SIMMONS states:

That I am President, Quality Assurance and Regulatory Affairs of **MEDLINE INDUSTRIES INC.**, hereinafter referred to as the Respondent, and make this application on Respondent's behalf.

That on or about February 21, 2007 Respondent was registered to operate as a pharmacy wholesaler in the State of New York, having been issued Registration No. 028250 by the New York State Education Department.

Respondent is currently registered with the New York State Education Department to operate as a pharmacy wholesaler in the State of New York from an address at: 3301 Route 6, Middletown, New York 10940.

Respondent has been charged with one (1) specification of professional misconduct, a copy of which is annexed hereto, made a part hereof, and marked as Exhibit "A". Respondent admits

guilt to the aforesaid specification of professional misconduct, charging it with having been found guilty of improper professional practice or professional misconduct by a duly authorized professional disciplinary agency of another state where the conduct upon which the finding was based would, if committed in New York State, constitute professional misconduct under the laws of New York State (findings of misconduct committed during the period 2008 to 2009 by three separate states which, if committed in New York, would constitute professional misconduct under the Education Law and Commissioner's Regulations).

Respondent hereby agrees to the penalty that it pay a fine in the amount of five thousand dollars ($5,000.00), said fine to be paid by certified or cashier's check, made payable to the order of the New York State Education Department, to be delivered to the Director, Office of Professional Discipline, 1411 Broadway, 10th Floor, New York, New York 10018-3496, within thirty (30) days after the effective date of the Order to be issued in this matter.

Respondent hereby makes this application to the Board of Regents and requests that it be granted.

Respondent understands that in the event that the Board of Regents denies the application, nothing contained herein shall be binding upon it or construed to be an admission of any act of misconduct alleged or charged against it. Such application shall

not be used against it in any way and shall be kept in strict confidence during the pendency of the disciplinary proceeding, and such denial by the Board of Regents shall be without prejudice to the continuance of the disciplinary proceeding and the final determination by the Board of Regents pursuant to the provisions of the Education Law.

Respondent agrees that in the event the Board of Regents grants its application, as set forth herein, an Order may be issued in accordance with the same. Respondent understands that if and when the Board of Regents grants this application, the entire application shall become a matter of public record.

No promises of any kind were made to Respondent. Respondent is making this application of its own free will and accord and not under duress, compulsion, or restraint of any kind or manner.

LARA N. SIMMONS

EXHIBIT "A"

MEDLINE INDUSTRIES INC.

SPECIFICATION OF PROFESSIONAL MISCONDUCT

Respondent is charged with having been found guilty of improper professional practice or professional misconduct by a duly authorized professional disciplinary agency of another state where the conduct upon which the finding was based would, if committed in New York State, constitute professional misconduct under the laws of New York State, within the purview and meaning of New York Education Law section 6509(5)(b), in that:

(a) On or about September 26, 2008, the Department of Health of the State of Florida, a duly authorized disciplinary agency of said state, issued a Final Order against the Respondent (Case No. 2007-11783);

(b) The conduct upon which said Final Order was based was that (1) Respondent failed to provide in a timely manner documents that were requested and (2) Respondent sold or transferred a legend drug to a person who was not authorized under the law of the jurisdiction in which the person received the drug to purchase or possess legend drugs from the Respondent;

(c) Said conduct, if committed in New York, would constitute professional misconduct under Section 6509(13) of the Education Law and Part 63.6(c)(5)

of the Commissioner's Regulations;

(d) On or about May 1, 2008, the Louisiana Board of Wholesale Drug Distributors, a duly authorized disciplinary agency of Louisiana, issued a Consent Order against the Respondent (Administrative Case No. 2008006);

(e) The conduct upon which said Consent Order was based was that Respondent failed to maintain current customer license documents and/or a current customer listing on-site;

(f) Said conduct, if committed in New York, would constitute professional misconduct under Part 63.6(c)(5) of the Commissioner's Regulations;

(g) On or about February 4, 2009, the Wisconsin Pharmacy Examining Board, a duly authorized disciplinary agency of Wisconsin, issued a Final Decision and Order (Case #08-PHM 037);

(h) The conduct upon which said Decision and Order was based was that when Respondent was inspected by the Wisconsin Department of Regulation and Licensing, it was found that certain policies were missing and that it was storing prescription drugs in a warehouse it shared with another company;

(i) Said conduct, if committed in New York, would constitute professional misconduct under Part 63.6(c)(4) of the Commissioner's Regulations and

Title 21, Section 205.50, Code of Federal Regulations (CFR).

NEW YORK STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE
STATE BOARD OF PHARMACY

----------X

IN THE MATTER

of the

Disciplinary Proceeding

against

MEDLINE INDUSTRIES INC.

which is currently registered to operate as a pharmacy wholesaler in the State of New York.

----------X

APPLICATION FOR CONSENT ORDER

CAL. NO. 27278

The undersigned agree to the above statement and to the proposed penalty based on the terms and conditions thereof.

MEDLINE INDUSTRIES INC.

Dated: 2/14, 2014

Respondent

BY:

Lara N. Simmons, President, Quality Assurance and Regulatory Affairs

Dated: 2/18, 2014

Attorney for Respondent

Dated: 2/27, 2014

Member, State Board of Pharmacy

Dated: 3/6, 2014

Executive Secretary
State Board of Pharmacy

Dated: 4/23, 2014

Director
Office of Professional Discipline

The undersigned, a member of the Board of Regents who has been designated by the Chairman of the Regents Committee on Professional Practice to review this Application for a Consent Order, has reviewed said Application and recommends to the Board of Regents that the Application be granted.

Dated: 5/7, 2014

Member, Board of Regents

:ds

Section 24.7 (b) For individuals served prior to June 20, 1997 with an order of revocation, acceptance of surrender, or denial of an application for restoration or reinstatement by vote of the Board of Regents, at least one year shall have elapsed from the date of such service for the acceptance by the department of a petition to the Board of Regents for restoration of a license or certificate, except that a period of time during which the license was suspended during the pendency of the discipline proceeding may reduce the one-year waiting period. For individuals served on or after June 20, 1997 with an with an order of revocation, acceptance of surrender, or denial of an application for restoration or reinstatement by vote of the Board of Regents, at least three years shall have elapsed from the date of such service for the acceptance by the department of a petition to the Board of Regents for restoration of a license or certificate, except that a period of time during which the license was suspended during the pendency of the discipline proceeding may reduce the three-year waiting period. This section shall not apply to restoration of licenses which have been temporarily surrendered pursuant to Education Law, section 6510-b, or Public Health Law, section 230(13).

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	01/06/2021	IL	Libertyville	Lake

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
A-2020-0054	Ohio Board of Pharmacy

Reason/Charge
Customer License

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Ohio Board of Pharmacy / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. distribution center at 1501 Harris Rd Libertyville, IL 60048 (OH License #01-1985050) entered into a settlement agreement with the Ohio Board of Pharmacy for the sale of dangerous drugs to an unlicensed entity. Medline maintained a current and valid DEA license on file rather than the correct Terminal Distributor Dangerous Drugs license (TDDD). The facility's TDDD license expired at the time of the sale. Case resolved via Settlement Agreement effective 01/06/2021.

Corrective Actions:
Medline updated its customer license requirements for Ohio customers. Medline completed a review of all Ohio customers to verify the correct license type was on file and implemented increased verification checks of Ohio licenses.

Original Signature (electronic, copies or stamps not accepted)

07/30/24
Date

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE No. A-2020-0054
I-2019-0972-B

Medline Industries, Inc.
c/o Willis Ingalls
1501 Harris Road
Libertyville, IL 60048

License No. 01-1985050

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Medline Industries, Inc. for the purpose of resolving all issues between the parties relating to the Board investigation of a selling dangerous drugs to an unlicensed entity. Together, the Board and Medline Industries are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Medline Industries, LLC, has an active WDDD license with the Board under license number 01-1985050, which lists Willis Ingalls as the Responsible Person.

FACTS

1. The Board initiated an investigation of Medline Industries, WDDD license number 01-1985050, related to the sale of dangerous drugs to an unlicensed entity.

2. On or about December 3, 2020, the Board sent a Notice of Opportunity for Hearing to Medline Industries, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Medline Industries neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated December 3, 2020, however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Medline Industries agrees to pay to the Board a monetary penalty the amount of $250.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. Medline Industries agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. Medline Industries agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Medline Industries of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Medline Industries by the Board and will NOT discharge Medline Industries from any obligation under the terms of this Agreement.

6. Medline Industries agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. Medline Industries understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Medline Industries will operate.

9. Medline Industries expressly waives its opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Willis A. Ingalls — 1-5-21

Willis Ingalls, on behalf of,
Medline Industries, Respondent — Date of Signature

Attorney for Respondent (if applicable) — Date of Signature

Jennifer Rudell, RPh — 1-6-2021

Jennifer M. Rudell, RPh, President,
State of Ohio Board of Pharmacy — Date of Signature

[signature] — 1-6-2021

Henry Appel, Ohio Assistant Attorney General — Date of Signature

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	06/28/2021	IL	Libertyville	Lake

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
21-L-0048	Alabama Board of Pharmacy

Reason/Charge
Discipline incurred in another jurisdiction

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Alabama Board of Pharmacy / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. distribution center at 1501 Harris Rd Libertyville, IL 60048 (AL Non-Resident Permit #193718) was fined for discipline incurred in another jurisdiction (OH A-2020-0054).

Original Signature (electronic, copies or stamps not accepted)

07/30/26
Date

Alabama Board of Pharmacy
111 Village Street
Birmingham AL 35242

USPS CERTIFIED MAIL



9414 8118 9876 5809 1318 98

MEDLINE INDUSTRIES, INC.
1501 HARRIS ROAD
LIBERTYVILLE IL 60048



$5.86 US POSTAGE
FIRST-CLASS
Jun 28 2021
Mailed from ZIP 35242
1 oz First-Class Mail Letter

11923275



062S0012913542

FO - 21-L-0048 193718

DocuSign Envelope ID: 7F8AA924-F79F-4BC6-A7E1-B16F9D238852

THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	
MEDLINE INDUSTRIES, INC.	)	BOARD OF PHARMACY
	)	
Wholesale Distributor Permit No. 193718	)	CASE NO: 21-L-0048

FINAL ORDER

On June 15, 2021, this cause came before the Alabama State Board of Pharmacy (hereinafter also referred to as the "Board"), on a Complaint against Medline Industries, Inc. (hereinafter also referred to as the "Respondent"). Evidence having been adduced thereon, the Board has determined that the following Findings of Fact and Conclusions of Law are supported by the preponderant weight of evidence and law.

Findings of Fact

1. The Respondent is a wholesale distributor permitted by this Board under Permit No. 193718. (Board Exhibit One)

2. The Respondent was properly notified of the charges on March 9, 2021. The Respondent did not appear at the scheduled hearing before the Board and was not represented by counsel at such hearing. (Board Exhibit One and Two)

3. The Respondent made no objection to the timeliness of the Notice of Hearing or the specificity of the Statement of Charges.

4. The Respondent violated Board Rules 680-X-2.23, 680-X-2.23(3), 680-X-2.23(3)(k)(1), 680-X-2.23(3)(k)(2), and 680-X-2.23(3)(k)(3) and Code of Alabama (1975), § 34-23-32 based upon Respondent's underlying conduct in its entry into a Settlement Agreement with the State of Ohio Board of Pharmacy dated January 6, 2021 (Attached) in which discipline was

DocuSign Envelope ID: 7F8AA924-F79F-4BC6-A7E1-B16F9D238852

imposed. In that Settlement Agreement, Respondent admitted that the State of Ohio Board of Pharmacy had evidence sufficient to sustain the allegations that Respondent made five (5) illegal sales of dangerous drugs to Columbus Podiatry & Surgery, Inc.

Conclusions of Law

1. The Alabama State Board of Pharmacy has jurisdiction of this cause pursuant to Code of Alabama (1975), § 34-23-,32 Code of Alabama (1975), § 34-23-92(12), and Code of Alabama (1975), § 41-22-12.

2. The Respondent was properly notified of the charges, failed to appear and was not represented by counsel at the administrative hearing. The Respondent did not contest the matter in any manner.

3. The Respondent made no objection to the timeliness of the Notice of Hearing or the specificity of the Statement of Charges.

4. The Respondent is due to be fined $500.00 in that it is guilty of violating Board Rules 680-X-2.23, 680-X-2.23(3), 680-X-2.23(3)(k)(1), 680-X-2.23(3)(k)(2), and 680-X-2.23(3)(k)(3) and Code of Alabama (1975), § 34-23-32 in regard to its conduct involving illegal sales of dangerous drugs which resulted in discipline/Settlement Agreement dated January 6, 2021 with the State of Ohio Board of Pharmacy.

ORDER

In accordance with the foregoing Findings of Fact and Conclusions of Law, it is hereby ORDERED as follows:

DocuSign Envelope ID: 7F8AA924-F79F-4BC6-A7E1-B16F9D238852

1. The Respondent is guilty as charged in Count One as contained in the Statement of Charges and Notice of Hearing and is hereby fined a total of Five Hundred ($500.00) Dollars.

2. The disciplinary fine of Five Hundred ($500.00) Dollars is due and payable to the Board within thirty (30) days of the date of this Final Order.

DONE and ORDERED, this 28th day of June, 2021.

Brenda R. Denson, Pharm.D., President
Alabama State Board of Pharmacy

Copies to:
Medline Industries, Inc.
Ms. Donna C. Yeatman, R. Ph., Executive Secretary
Mr. James S. Ward, Esq.
Mr. James F. Hampton, Esq.
Mr. Vance L. Alexander, Esq.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
	11/01/2022	OH	West Jefferson	Madison

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
A-2022-0333	Ohio Board of Pharmacy

Reason/Charge
Customer Licenses

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Ohio Board of Pharmacy / Medline Industries, LP	Administrative Action

Name of Business/Industry/Entity
Medline Industries, LP

Provide explanation below:

Medline Industries, LP distribution center at 1040 Enterprise Parkway South, West Jefferson, OH 43162 (OH License #01-30000190) entered a settlement agreement with the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file instead of the correct Terminal Distributor Dangerous Drugs license (TDDD). The TDDD license was added in May 2022. During the period of July 2021 to March 2022, the customer's TDDD license lapsed, and Medline shipped the customer product under the valid practitioner license. Case resolved via Settlement Agreement effective 11/01/2022.

Corrective Actions:
Medline updated customer licensing requirements for Ohio customers following OH Case # A-2020-0054. The shipments in this matter occurred while Medline was in the process of reviewing and updating all Ohio customer licenses. Medline licensing staff were also provided with additional training on Ohio license requirements.

Original Signature (electronic, copies or stamps not accepted)

07/30/26
Date

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. A-2022-0333
I-2022-0624

Medline Industries, LP
c/o James Eveland
1040 Enterprise Parkway South
West Jefferson, OH 43162

License No. 01-30000190

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Medline Industries, LP, for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of dangerous drugs to an unlicensed entity. Together, the Board and Medline Industries, LP are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Medline Industries, LP, is a licensed Distributor of Dangerous Drug, License No. 01-30000190, which lists James Eveland, as the Responsible Person.

FACTS

1. The Board initiated an investigation of Medline Industries, LP, Distributor of Dangerous Drugs License No. 01-30000190, related to Medline Industries, LP's illegal sales of dangerous drugs to an unlicensed entity.

2. On or about September 28, 2022, the Board sent a Notice of Opportunity for Hearing to Medline Industries, LP, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Medline Industries, LP neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated September 28, 2022; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Medline Industries, LP agrees to pay to the Board a monetary penalty in the amount of $1,125.00. This fine will be attached to your license record and must be paid no later than 180 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. The Board hereby imposes a written reprimand on Medline Industries, LP's WDDD license, number 01-30000190.

5. Medline Industries, LP agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

6. Medline Industries, LP agrees to comply with all federal and state requirements related to Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Medline Industries, LP of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Medline Industries, LP by the Board and will NOT discharge Medline Industries, LP from any obligation under the terms of this Agreement.

7. Medline Industries, LP agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. Medline Industries, LP understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Medline Industries, LP will operate.

10. Medline Industries, LP waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

14. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

15. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

James Eveland, on behalf of,
Medline Industries, LP, Respondent

10-25-2022
Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

Shawn Wilt, RPh, President,
State of Ohio Board of Pharmacy

11.1.2022
Date of Signature

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	12/19/2022	FL	Miami	Miami-Dade

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
A-2022-0333	FL DBPR- Div. of Drugs, Devices, and Cosmetics

Reason/Charge
Customer Licenses, Record Keeping

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
FL DBPR / Medline Industries, LP	Administrative Action

Name of Business/Industry/Entity
Medline Industries, LP

Provide explanation below:

Medline Industries, LP distribution center at 9670 NW 112th Ave, Miami, FL 33178 (FL WDD# #2220297) entered a settlement agreement for alleged violations of selling prescription drugs to an unauthorized recipient and failure to maintain proper records. Medline accepted a physician license for a customer which should have maintained a Healthcare Clinic Establishment Permit. The recordkeeping allegation related to missing NDC numbers on outbound packing slips and invoices.

Corrective Actions:
Medline updated customer licensing requirements for Florida customers and completed an extensive review of all FL customer licenses to verify the correct license type was on file. Medline determined the missing NDC number on the packing slip and invoice occurred due to an internal system error. The error was limited to DSCSA exempt products, i.e. IV fluids. A fix was implemented to correct the issue.

Original Signature (electronic, copies or stamps not accepted)

07/30/26
Date

FILED
Department of Business and Professional Regulation
Senior Deputy Agency Clerk
CLERK: Brandon Nichols
Date: 12/21/2022
File #: 2022-09829

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner,

v. **Case No.: 2022-031132**

MEDLINE INDUSTRIES, LP,

Respondent,
_____/

FINAL ORDER

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics ("the Department"), in accordance with the provisions of Section 120.57(4), Florida Statutes, hereby enters this Final Order incorporating and adopting, *in toto*, the Settlement Agreement entered into between Medline Industries, LP, and the Department, attached hereto and incorporated by reference.

This Final Order is effective on the date it is filed with the Agency Clerk of the Department as indicated on this Final Order.

DONE and ORDERED this 19th day of December, 2022 in Tallahassee, Florida.

MELANIE S. GRIFFIN, SECRETARY

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

By: _____
Walter S. Copeland, Director
Division of Drugs, Devices, and Cosmetics

Prepared by:

Anthony Coniglio
DDC Chief Attorney

NOTICE OF RIGHT TO APPEAL

Unless expressly waived, any party adversely affected by this Final Order may seek judicial review by filing an original Notice of Appeal with the Clerk of the Department of Business & Professional Regulation, and a copy of the Notice, accompanied by the filing fees prescribed by law, with the clerk of the appropriate District Court of Appeal within 30 days of the effective date of this order, in accordance with Florida Rule of Appellate Procedure 9.110, and Section 120.68, Florida Statutes.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of this Final Order has been provided by regular US mail to: Corporation Service Company, Registered Agent for Medline Industries, LP, 1201 Hays Street, Tallahassee, Florida 32301 on this 21st day of December, 2022.

By: Brandon M. Nichols
Agency Clerk's Office

RECEIVED
NOV 09 2022
DRUGS, DEVICES AND COSMETICS

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner, **Case No.: 2022-031132**

v.

MEDLINE INDUSTRIES, LP,

Respondent.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the above-named parties hereby enter into this Settlement Agreement (hereinafter, "this agreement") as disposition of the alleged violations described in the Notice of Violation in case number 2022-031132 (hereinafter, "the allegations"). The terms herein become effective upon rendition of the final order, which shall incorporate this agreement.

The State of Florida, Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (hereinafter, "the Department") is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 20.165 and Chapter 499, Florida Statutes.

STIPULATED FACTS

1. Medline Industries, LP (hereinafter, "Respondent") is permitted by the Department as a prescription drug wholesale distributor, having been issued permit number 22:20297.

2. Respondent's address of record is 9670 Northwest 112th Avenue, Miami, Florida 33178.

3. Respondent was issued a Notice of Violation on October 26, 2022, alleging that it committed certain violations of Chapter 499, Florida Statutes, and the administrative rules adopted

pursuant thereto.

CONCLUSIONS OF LAW

4. Respondent, by and through its undersigned agent, admits that it is subject to the applicable provisions of Chapter 499, Florida Statutes, and the relevant jurisdiction of the Department.

5. Respondent neither admits nor denies the allegations in the Notice of Violation issued in case number 2022-031132, but enters into this agreement for the purpose of resolving the issues raised by the Department.

SETTLEMENT TERMS

6. Respondent affirms that it is currently in compliance with Chapter 499, Florida Statutes.

7. Respondent agrees to pay a settlement amount of six thousand dollars ($6,000.00). **Payment of the settlement amount shall be made only by corporate check, cashier's check, or money order to the Professional Regulation Trust Fund, and shall be remitted to The Florida Department of Business & Professional Regulation, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, Florida 32399-1047, Attention: Kimberley Johnson, Senior Legal Assistant**. Respondent acknowledges that payment is enclosed with this agreement. The payment and execution of this agreement by Respondent are absolute conditions precedent to the Department's execution of this agreement.

8. The acceptance of this agreement constitutes disciplinary action within the meaning of Section 499.066, Florida Statutes and Rule 61N-1.024, Florida Administrative Code.

STANDARD PROVISIONS

9. It is expressly understood that a violation of the terms of this agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary action may be taken.

10. The parties agree that this agreement will be incorporated into a final order that will be filed with the Department agency clerk and will be a public document. The final order will contain no material terms other than those in this agreement. **The final order shall operate to close case number 2022-031132. The final order shall be the final disposition in this proceeding and shall constitute final agency action with respect thereto.**

11. Respondent expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this agreement and the final order in which this agreement is incorporated, provided the final order does not conflict with this agreement.

12. Each party waives the right to seek any attorney's fees or costs from the other party in connection with this proceeding.

13. This agreement may be executed in any number of counterparts including, without limitation, telecopies and facsimile transmission copies, all of which together shall constitute a single document.

14. The parties agree that this agreement represents a fair, appropriate, and reasonable resolution to, and final disposition of, all disputes and matters made subject hereof.

15. The terms and provisions of this agreement are severable and, if any term or provision is declared or deemed void, invalid, illegal, or otherwise unenforceable, then all remaining terms and provisions shall remain in full force and effect.

16. It is expressly understood that this agreement is subject to approval of the Division of Drugs, Devices, and Cosmetics, and has no force or effect until the Division accepts this

agreement and adopts it in a final order.

17. The signatories hereto are vested with the authority to execute this agreement on behalf of their respective principals and, as duly designated representatives, to fully bind such principals.

MEDLINE INDUSTRIES, LP,

By: _____

Name: Daniel Stevens

Title: Manager Regulatory Affairs

Date: 11/18/2022

FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION DIVISION OF DRUGS, DEVICES, AND COSMETICS,

By: _____

Name: Walter Copeland

Title: Division Director

Date: 12.19.2022

Prepared by:

Anthony Coniglio
DDC Legal Chief
Division of Drugs, Devices, and Cosmetics

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
2601 Blair Stone Road
Tallahassee, Florida 32399
www.MyFloridaLicense.com



Corporation Service Company
Registered Agent for Medline Industries, LP
1201 Hays Street
Tallahassee, Florida 32301

Case No: 2022-031132 (Final Order)

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	07/25/2023	OH/IN	See Below	See Below

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
A-2022-0307; A-2022-0184	Ohio Board of Pharmacy

Reason/Charge
Customer Licenses

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Ohio Board of Pharmacy / Medline Industries, LP	Administrative Action

Name of Business/Industry/Entity
Medline Industries, LP

Provide explanation below:

Medline Industries, LP distribution centers at 1040 Enterprise Parkway South, West Jefferson, OH 43162 (OH License #01-30000190) and 251 Hilton Drive. Jeffersonville, IN 47130 (OH License #01-30000158) entered settlement agreements with the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. The sales occurred between July 2021 and January 2022. Medline maintained valid practitioner licenses on file for each customer instead of the correct d sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file instead of the correct Terminal Distributor Dangerous Drugs license (TDDD). Cases resolved via Settlement Agreement effective 07/19/2023 and 07/25/2023.

Corrective Actions:
Medline updated customer licensing requirements for Ohio customers following OH Case # A-2020-0054. The shipments in this matter occurred between July 2021 and January 2022 while Medline was in the process of reviewing and updating all Ohio customer licenses.

Locations:
1040 Enterprise Parkway South, West Jefferson, OH 43162 (Madison County)
251 Hilton Drive, Jeffersonville, IN 47130 (Clark County)

Original Signature (electronic, copies or stamps not accepted)

07/30/26
Date

STATE OF OHIO
BOARD OF PHARMACY

July 19, 2023

Medline Industries, LP
c/o James Eveland
1040 Enterprise Parkway South
West Jefferson, OH 43162

Re: Settlement Agreement
License No. 01-30000190

Dear Mercy Primary Care Portage,

Enclosed you will find your Settlement Agreement with the State of Ohio Board of Pharmacy. This document is signed and effective as of July 19, 2023. If you have any questions or concerns, please do not hesitate to contact the Board of Pharmacy and ask to speak with someone in the Legal Department.

Sincerely,

Jennifer Nelson

Jennifer Nelson
Legal Administrative Assistant

Enclosure: July 19, 2023 Settlement Agreement with the State of Ohio Board of Pharmacy

CMRRR: 9414 7118 9956 2233 7395 37

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. A-2022-0307
I-2022-0168

Medline Industries, LP
c/o James Eveland
1040 Enterprise Parkway South
West Jefferson, OH 43162

License No. 01-30000190

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Medline Industries, LP, for the purpose of resolving all issues between the parties relating to the Board investigation of sales of dangerous drugs to unlicensed entities. Together, the Board and Medline Industries, LP are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Medline Industries, LP, is a licensed Distributor of Dangerous Drug, License No. 01-30000190, which lists James Eveland, as the Responsible Person.

FACTS

1. The Board initiated an investigation of Medline Industries, LP, Distributor of Dangerous Drugs License No. 01-30000190, related to Medline Industries, LP's illegal sales of dangerous drugs to an unlicensed entity.

2. On or about 11/16/2022, the Board sent a Notice of Opportunity for Hearing to Medline Industries, LP, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Medline Industries, LP neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated 11/16/2022; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Medline Industries, LP agrees to pay to the Board a monetary penalty in the amount of $875.00.00. This fine will be attached to your license record and must be paid no later than 60 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. The Board hereby imposes a written reprimand on Medline Industries, LP 's WDDD license, number 01-30000190.

5. Medline Industries, LP agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

6. Medline Industries, LP agrees to comply with all federal and state requirements related to Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Medline Industries, LP of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Medline Industries, LP by the Board and will NOT discharge Medline Industries, LP from any obligation under the terms of this Agreement.

7. Medline Industries, LP agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. Medline Industries, LP understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Medline Industries, LP will operate.

10. Medline Industries, LP waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

14. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

15. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

James Eveland, on behalf of, Medline Industries, LP, Respondent	7-11-23 Date of Signature
Attorney for Respondent (if applicable)	Date of Signature
Trina Buettner, RPh, President, State of Ohio Board of Pharmacy	07.19.2023 Date of Signature

STATE OF OHIO
BOARD OF PHARMACY

July 25, 2023

Medline Industries
c/o Filomena Kropiweic
251 Hilton Dr.
Jeffersonville, IN 47130

Re: Settlement Agreement
License No. 0130000158

Dear Medline Industries,

Enclosed you will find your Settlement Agreement with the State of Ohio Board of Pharmacy. This document is signed and effective as of July 25, 2023. If you have any questions or concerns, please do not hesitate to contact the Board of Pharmacy and ask to speak with someone in the Legal Department.

Sincerely,

Jennifer Nelson

Jennifer Nelson
Legal Administrative Assistant

Enclosure: July 25, 2023 Settlement Agreement with the State of Ohio Board of Pharmacy

CMRRR: 9414 7118 9956 2027 4018 31

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE No. A-2022-0184
I-2021-1908

Medline Industries
c/o Filomena Kropiweic
251 Hilton Drive
Jeffersonville, IN 47130

License No. 01-30000158

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Medline Industries, for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of dangerous drugs to an unlicensed entity. Together, the Board and Medline Industries are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Medline Industries is a licensed Distributor of Dangerous Drug, License No. 01-30000158, which lists Filomena Kropiweic as the Responsible Person.

FACTS

1. The Board initiated an investigation of Medline Industries, Distributor of Dangerous Drugs License No. 01-30000158, related to Medline Industries' illegal sales of dangerous drugs to an unlicensed entity.

2. On or about April 25, 2023, the Board sent a Notice of Opportunity for Hearing to Medline Industries, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Medline Industries neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated April 25, 2023; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Medline Industries agrees to pay to the Board a monetary penalty in the amount of $750.00. This fine will be attached to your license record and must be paid no later than 60 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. The Board hereby imposes a written reprimand on Medline Industries' WDDD license, number 01-30000158.

5. Medline Industries agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

6. Medline Industries agrees to comply with all federal and state requirements related to Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Medline Industries of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Medline Industries by the Board and will NOT discharge Medline Industries from any obligation under the terms of this Agreement.

7. Medline Industries agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. Medline Industries understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Medline Industries will operate.

10. Medline Industries waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

14. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

15. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Filomena Kropiweic — Filomena Kropiweic, on behalf of, Medline Industries, Respondent

06-29-2023 — Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

07.25.2023

Trina Buettner, RPh, President, State of Ohio Board of Pharmacy

Date of Signature

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	12/21/2023	HI	Kapolei	Honolulu

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
PHA 2023-9-L	Hawaii Department of Commerce and Consumer Affairs

Reason/Charge
Discipline incurred in another jurisdiction

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
HI DCCA / Medline Industries, LP	Administrative Action

Name of Business/Industry/Entity
Medline Industries, LP

Provide explanation below:

Medline Industries, LP distribution center at 2341 Lauwiliwili St, Kapolei, HI 96707 (HI #) entered a Settlement Agreement for discipline incurred in another jurisdiction (OH A-2022-0333, OH A-2022-0307, OH A-2022-0184, and FL 2022-031132)

Original Signature (electronic, copies or stamps not accepted)

07/30/24
Date

IVY Y. E. KIM 9609
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 S. Beretania Street, 9th Floor
Honolulu, Hawaii 96813
Telephone: (808) 586-2660
E-mail: ikim@dcca.hawaii.gov

Attorney for Department of Commerce
and Consumer Affairs

2023 DEC 15 A 11:07
DEPT. OF COMMERCE AND CONSUMER AFFAIRS
2023 DEC 29 P 12:37
HEARINGS OFFICE

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Wholesale Prescription Drug Distributor License of MEDLINE INDUSTRIES, L.P., Respondent.	PHA 2023-9-L SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" – "3"

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney and Respondent MEDLINE INDUSTRIES, L.P. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was licensed as a wholesale prescription drug distributor by the Board of Pharmacy (hereinafter the "Board") under the license number PWD-193. The license was issued on or about May 16, 2022. The license will expire or forfeit on or about December 31, 2023, unless timely renewed.

2. Respondent's mailing address for purposes of this action is 2341 Lauwiliwili Street, Kapolei, Hawaii 96707.

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

3. On or about December 19, 2022, the Florida Department of Business & Professional Regulation (hereinafter "Department") issued a Final Order adopting the Settlement Agreement entered into between Respondent and the Department in Case No. 2022-031132 (hereinafter the "Florida Final Order"). The Florida Final Order was based on Respondent's alleged selling of prescription drugs to an unauthorized recipient, failure to maintain records, and failure to provide required documentation to customers. The Florida Final Order is attached hereto as Exhibit "1".

4. On or about July 19, 2023, Respondent and State of Ohio Board of Pharmacy entered into a Settlement Agreement in Case No. A-2022-0307, I-2022-0168, related to Respondent's illegal sales of dangerous drugs to an unlicensed entity. The Settlement Agreement is attached hereto as Exhibit "2".

5. On or about July 25, 2023, Respondent and State of Ohio Board of Pharmacy entered into a Settlement Agreement in Case No. A-2022-0184, I-2021-1908, related to Respondent's illegal sales of dangerous drugs to an unlicensed entity. The Settlement Agreement is attached hereto as Exhibit "3".

6. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes (hereinafter "HRS") § 436B-19(13) (disciplinary action by another state or federal agency).

7. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing, and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent, being at all times relevant herein licensed as a wholesale prescription drug distributor by the Board, acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the license and administrative fines, if the foregoing allegations are proven at hearing. Respondent further understands that RICO enters into this Settlement Agreement and agrees to the specific terms contained in this Settlement Agreement, based upon Respondent's representations made herein.

5. Respondent represents that Exhibits "1" – "3" are true and correct copies of the purported Florida Final Order and Settlement Agreements with the Ohio Board of Pharmacy.

6. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this Settlement Agreement may be grounds for further disciplinary action under HRS Chapters 436B and 461.

7. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's license.

8. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

9. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2023-9-L.

10. Respondent understands that this Settlement Agreement may be subject to reporting requirements.

11. Respondent understands this Settlement Agreement is public record pursuant to HRS Chapter 92F.

12. Respondent acknowledges that upon tis approval, this Settlement Agreement constitutes disciplinary action.

C. TERMS OF SETTLEMENT:

1. Administrative Fine. Respondent agrees to pay an administrative fine in the amount of TWO THOUSAND TWO HUNDRED FIFTY AND NO/100 DOLLARS ($2,250.00). Payment shall be made by **cashier's check or money order made payable to "DCCA – Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn.: Ivy Y. E. Kim, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph C.1. above, Respondent's license shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of licensure to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new license until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become licensed again, Respondent must apply to the Board for a new license pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible Further Sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board

may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of pharmacies in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5., C.6., and C.7. below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent, nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion, or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion, or promise made by RICO or any of its agents, employees, representatives, or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

[Remainder of this page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below. Each signatory to this Settlement Agreement hereby represents and warrants that he/she is authorized to execute and deliver this Settlement Agreement in the capacity shown below.

DATED: Northfield (City), IL (State), 09/07/2023 (Date).

MEDLINE INDUSTRIES, L.P.
Respondent

By: _____ (Signature)

Daniel Stevens (Print Name)

Its Manager Regulatory Affairs (Print Title)

DATED: Honolulu, Hawaii, 10/11/2023.

_____

IVY Y. E. KIM
Attorney for Department of Commerce
and Consumer Affairs

IN THE MATTER OF THE WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR LICENSE OF MEDLINE INDUSTRIES, L.P.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" – "3"; RICO CASE NO. PHA 2023-9-L.

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

ALANNA ISOBE Chair	December 21, 2023 **DATE**
PATRICK ADAMS Vice Chair	**MARK BROWN**
CATALINA CROSS	Kent Kikuchi **KENT KIKUCHI**
BRANDON RABANG	**SHERI TOKUMARU**

PVL 11/09/22

POWER OF ATTORNEY

MEDLINE INDUSTRIES, LP, an Illinois limited partnership, having a principal place of business at 3 Lakes Drive, Northfield, Illinois, 60093 (the "Company"), herewith authorize and entrust a Power of Attorney to DANIEL A. STEVENS, United States citizen, Manager Regulatory Affairs, with permanent residence at 4217 Arlington Avenue, Sacramento, CA 95820 with full signatory rights on behalf of the Company as follows:

To be our true and lawful Agent with as full as legally necessary powers to submit, execute and prosecute applications in the name of the Company, for permits, registrations and other governmental authorizations, relating in any way to the quality assurance, quality control, regulatory, warehousing and sterilizing functions of the Company, and to represent the Company and take all necessary actions in legal matters and all other matters towards all third parties and all public authorities, federal, state or municipal, and towards all other divisions, subdivisions, departments, units or all secretariats of the above, relating in any way to the quality assurance, quality control, regulatory, warehousing and sterilizing functions of the Company.

This power of Attorney is valid until revoked in writing by the Company.

Dated: October 11, 2022

Medline Industries, LP

By: Mozart GP, LLC
Its: General Partner

By: _____
Name: Alexander M. Liberman
Title: Assistant Secretary

ACKNOWLEDGEMENT

STATE OF ILLINOIS
COUNTY OF COOK

This instrument was acknowledged before me on October 11, 2022 by Alexander M. Liberman, as Assistant Secretary of Mozart GP, LLC, as General Partner of Medline Industries, LP.

Barbara Bychowski
(Signature of Notary Public)

(Seal)

"OFFICIAL SEAL"
BARBARA BYCHOWSKI
NOTARY PUBLIC, STATE OF ILLINOIS
MY COMMISSION EXPIRES 8/29/2025

4F

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

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

Section 1: General Information

Facility Name: Medline Industries, LP

Physical Address: 92 SE 223rd Ave.

City: Gresham State: OR Zip: 97030

Mailing Address (if different from physical address): Three Lakes Drive - 3D

City: Northfield State: IL Zip: 60093

Telephone: 503-665-5824 Website: www.medline.com

Name of Designated Representative (DR): Mark Cardoos

Licensing Company Email: ralicensing@medline.com DR Email: mcardoos@medline.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☒ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☒ Warehouse
☒ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Assisted living, nursing homes, surgical centers.		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Pfizer, Inc.
Address: 66 Hudson Blvd. E City: New York State: NY Zip: 10001

Name: ICU Medical Inc.
Address: 951 Calle Amanecer City: San Clemente State: CA Zip: 92673

Name: Baxter Healthcare Inc.
Address: One Baxter Parkway City: Deerfield State: IL Zip: 60015

Name: B Braun Medical Inc.
Address: 824 12th Avenue City: Bethlehem State: PA Zip: 18018

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): Medline Inc.
Corporation Name: See Attached Ownership Information
Mailing Address: Three Lakes Drive
City: Northfield State: IL Zip: 60093
Telephone: 847-949-5500 Email: ralicensing@medline.com
Contact Person Name: Daniel Stevens (916) 292-0005

Date of SEC Registration: 12/17/2025 | SEC Registration Number: 0002046386 | Stock Exchange Symbol: MDLN

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		X
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
N/A • **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Medline Industries, LP

Facility Name

Daniel Stevens - Manager of Regulatory Affairs (POA)

Print Name of Authorized Person Submitting Application

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

08/10/26

Date

Board Use Only	Date Received: 8/17/26	Amount: $1000-cc

POWER OF ATTORNEY

MEDLINE INDUSTRIES, LP, an Illinois limited partnership, having a principal place of business at 3 Lakes Dr, Northfield, Illinois, 60093 (the "Company"), herewith authorizes and entrusts a Power of Attorney to DANIEL A. STEVENS, United States citizen, Manager, Regulatory Affairs, with permanent residence at 4369 Vulcan Drive, Sacramento, California 95864 with full signatory rights on behalf of the Company as follows:

To be our true and lawful Agent with as full as legally necessary powers to submit, execute and prosecute applications in the name of the Company, for permits, registrations and other governmental authorizations, relating in any way to the quality assurance, quality control, regulatory, warehousing, distribution, licensing, and sterilizing functions of the Company, and to represent the Company and take all necessary actions in legal matters and all other matters towards all third parties and all public authorities, federal, state or municipal, and towards all other divisions, subdivisions, departments, units or all secretariats of the above, relating in any way to the quality assurance, quality control, regulatory, warehousing, distribution, licensing, and sterilizing functions of the Company.

This Power of Attorney is valid until revoked in writing by the Company.

Dated: January 21, 2026

Medline Industries, LP
By: Mozart GP, LLC
Its: General Partner

By: ML
Name: Alexander M. Liberman
Title: Chief Legal Officer and Secretary

ACKNOWLEDGEMENT

STATE OF ILLINOIS
COUNTY OF COOK

This instrument was acknowledged before me on January 21, 2026 by Alexander M. Liberman, as Chief Legal Officer and Secretary of Mozart GP, LLC, as General Partner of Medline Industries, LP.

Barbara Theresa Bychowski
(Signature of Notary Public)

(Seal)

OFFICIAL SEAL
Barbara Theresa Bychowski
NOTARY PUBLIC, STATE OF ILLINOIS
Commission No. 1016211
My Commission Expires August 28, 2029

Medline Industries, LP

FEIN: 36-2596612

An Illinois Limited Partnership

Contact Information:

Three Lakes Drive
Attn: RA Licensing – 3D
Northfield, IL 60093
Ralicensing@medline.com
847-949-5500

Partners:

Partner	General or Limited	Business Address	% of Ownership	FEIN
Medline Borrower, LP	Limited	Three Lakes Drive, Northfield, IL 60093	100%	87-2530238
Mozart GP, LLC	General	Three Lakes Drive, Northfield, IL 60093	0%	87-2508203

Officers of General Partner - Mozart GP, LLC:

Name	Title	Home Address	SSN	DOB
James M. Boyle	Chief Executive Officer	[redacted]		
Stephen L. Miller	Chief Operating Officer			
Michael B. Drazin	Chief Financial Officer			
Alexander M. Liberman	General Counsel, Secretary			

Attachment 2

Medline Inc.

FEIN: IL 33-185288

Contact Information:
3 Lakes Drive
Attn: RA Licensing – 3D
Northfield, IL 60093
Ralicensing@medline.com
847-949-5500

Officers and Directors:
Information as of 07/09/2026

Officers

Name	Title
James M. Boyle	Chief Executive Officer
Michael B. Drazin	Chief Financial Officer
Stephen L. Miller*	Chief Operating Officer
Alexander M. Liberman	Chief Legal Officer
Douglas P. Golwas	Chief Commercial Officer
Christopher P. Shryock	Chief Human Resources Officer
Amanda Hutton Laabs	Chief Product Officer
Jessi Corcoran	Chief Accounting Officer
William J. Abrams	Executive Vice President, Supply Chain Solutions

*On July 7, 2026, Stephen L. Miller, Chief Operating Officer of Medline Inc. (the "Company"), notified the Company that he would retire from his role, effective August 30, 2026/ The Company is launching a search for his successor.

Directors

Name	Title
Charles N. Mills	Non-Executive Chair of the Board
Andrew J. Mills	Director
Anushka M. Sunder	Director
Jacob D. Best	Director
James M. Boyle	Director
Joseph P. Baratta	Director
Patrick J. Healy	Director
Richard A. Galanti	Director
Robert R. Schmidt	Director
Stephen H. Wise	Director
Thomas W. Sweet	Director
Todd N. Bluedorn	Director

Attachment 3

Medline Inc.
Top Four Shareholders

Medline Inc.
Medline Inc. is a U.S. publicly traded company trading under the ticker symbol MDLN on Nasdaq. Medline Inc. publicly reports beneficial holders of 5% or more of its outstanding securities ("significant stockholders") in its filings with the U.S. Securities and Exchange Commission ("SEC"), which are available at www.sec.gov/edgar/browse/?CIK=2046386. Medline Inc. reports this information in accordance with SEC rules, including in reliance on public reporting of ownership by its significant stockholders.

Top Four Shareholders of Medline Inc. as of May 4, 2026

Name of Beneficial Owner	Combined Voting Power
Mozart HoldCo, Inc.[1]	17.8%
Blackstone[2]	14.2%
Carlyle[3]	14.2%
H&F[4]	14.2%

[1] Mozart HoldCo, Inc. is an entity that is owned directly and/or indirectly by members of the Mills Family and trusts for their benefit.
[2] "Blackstone" refers to certain entities and/or funds associated with Blackstone Inc.
[3] "Carlyle" refers to certain entities and/or funds associated with The Carlyle Group Inc.
[4] "H&F" refers to certain entities and/or funds associated with Hellman & Friedman LLC

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "MEDLINE INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRD DAY OF APRIL, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "MEDLINE INC." WAS INCORPORATED ON THE SIXTH DAY OF NOVEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5143163 8300

SR# 20261572157

Authentication: 203550646

Date: 04-03-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

Attachment 4

File Number S030704

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias,** *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

MEDLINE INDUSTRIES, LP, HAVING REGISTERED IN THE STATE OF ILLINOIS ON SEPTEMBER 07, 2021, APPEARS TO HAVE COMPLIED WITH ALL PROVISIONS OF THE UNIFORM LIMITED PARTNERSHIP ACT (2001) OF THIS STATE, AND AS OF THIS DATE IS IN GOOD STANDING AS A DOMESTIC LP/LLLP IN THE STATE OF ILLINOIS, HAVING FULFILLED ALL REQUIREMENTS OF SAID ACT WITH REGARD TO PAYMENT OF FEES, THE FILING OF ANNUAL REPORTS (IF APPLICABLE) AND NEITHER HAVING BEEN ADMINISTRATIVELY DISSOLVED BY THE SECRETARY OF STATE NOR HAVING VOLUNTARILY FILED A STATEMENT OF TERMINATION.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 15TH *day of* APRIL *A.D.* 2026 .

SEAL OF THE STATE OF ILLINOIS — UNION — NATIONAL — INDIVISIBLE — STATE — 1868 — 1818 — AUG. 26TH 1818

Authentication #: 2610502528 verifiable until 04/15/2027
Authenticate at: https://www.ilsos.gov

Alexi Giannoulias
SECRETARY OF STATE

State of Oregon

OFFICE OF THE SECRETARY OF STATE
Corporation Division

Certificate of Existence 8127474

I, TOBIAS READ, SECRETARY OF STATE and Custodian of the Seal of said State, do hereby certify:

MEDLINE INDUSTRIES, LP

is

Filed

under the laws of The State of Oregon

and is active on the records of the Corporation Division as of the date of this certificate.

In Testimony Whereof, I have hereunto set my hand and affixed hereto the Seal of the State of Oregon.

TOBIAS READ, SECRETARY OF STATE

Issued Date: 8/11/2026

Come visit us on the internet at: https://sos.oregon.gov/business or use the QR code to check their current status.

Licensee Details

Demographic Information

Name: MEDLINE INDUSTRIES LP
Owner Name:

Address Information

Line 1: 92 SE 223RD AVE
Line 2:
Line 3:
Line 4: Gresham OR 97030

License Information

Type: Wholesaler with Prescription
Lic #: W1-0004733
Status: Active
Issued: 12/13/2018
Expiration Date: 9/30/2027
Last Renewed: 8/26/2026

Small Business?	N	N	Y

Prerequisite Information

Relationship/Name	Dates	License Details

Specialty Information

No Specialty Information

Discipline Information

No Discipline Information

Board Orders

No Available Board Orders

Attachment 8

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 06/22/2026

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

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

PRODUCER
MARSH USA LLC.
155 N. WACKER, SUITE 1200
CHICAGO, IL 60661

CN101705524-Stnd-GAWUP-26-27 USA

INSURED
Medline Industries, LP
3 Lakes Dr
Northfield, IL 60093

CONTACT NAME: Medline Industries, LP
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS: riskmanagement@medline.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Safety National Casualty Corporation	15105
INSURER B : Endurance Assurance Corporation	11551
INSURER C : See Acord 101 for Carrier Participation	
INSURER D :	
INSURER E :	
INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** CHI-008956355-45 **REVISION NUMBER:** 80

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			GL 4065036	07/01/2026	07/01/2027	EACH OCCURRENCE	$	2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	2,000,000
							MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	4,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	SEE BELOW
	OTHER:							$	
A	AUTOMOBILE LIABILITY			CA 6675933	07/01/2026	07/01/2027	COMBINED SINGLE LIMIT (Ea accident)	$	2,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
B	X UMBRELLA LIAB X OCCUR			ELD10004065213	07/01/2026	07/01/2027	EACH OCCURRENCE	$	10,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$	10,000,000
	DED X RETENTION $ 10,000							$	
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			LDS 4065032 (AOS)	07/01/2026	07/01/2027	X PER STATUTE OTH-ER		
A	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y / N: Y	N / A		PS 4065034 (WI)	07/01/2026	07/01/2027	E.L. EACH ACCIDENT	$	1,000,000
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
C	Products/Completed Operations Liability			LSR-PCO-00678-26	07/01/2026	07/01/2027	Limit		2,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Re: C42 - 3446 Highway 51 N Southaven, MS 38672. C40- 81 Campanelli Dr, Uxbridge, MA 01569.
SIR applies per policy terms & conditions. The products/completed operations policy evidenced above is subject to self-insured retentions for various perils covered.
Evidence of Insurance.

CERTIFICATE HOLDER
Medline Industries, LP
3 Lakes Dr.
Northfield, IL 60093

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

AUTHORIZED REPRESENTATIVE
Marsh USA Inc.

© 1988-2016 ACORD CORPORATION. All rights reserved.

AGENCY CUSTOMER ID: CN101705524
LOC #: Chicago

ACORD®

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC.	Medline Industries, LP 3 Lakes Dr Northfield, IL 60093
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

LOCATION ADDRESS CITY STATE ZIP CODE
B01 1 Medline Pl. Mundelein Illinois 60060
B04 1160 S Northpoint Blvd S . Waukegan Illinois 60085
B04 1710 S Lakeside Dr. Waukegan Illinois 60085
B04 1170 S Northpoint Blvd S. Waukegan Illinois 60085
B06 1 Medline Dr. Wilmer Texas 75172
B11 21111 E 36th Dr. Aurora Colorado 80011
B18 1062 Fasken Blvd. Laredo Texas 78045
B22 9670 NW 112 Ave. Medley Florida 33178
B24 8001 SW 47th St. Oklahoma City Oklahoma 73179
B25 1401 N Universal Ave. Kansas City Missouri 64120
B27 92 SE 223rd Ave. Gresham Oregon 97030
B28 735 County Rd 4 E. Prattville Alabama 36067
B29 13115 Brockton Lane N. Rogers Minnesota 55374
B30 1900 Meadowville Technology Parkway. Chester Virginia 23836
B31 500 Sharkey Dr. Maumelle Arkansas 72113
B34 9051 King St. Anchorage Alaska 99518
B36 1989 Transit Way. Brockport New York 14420
B44 2325 W Louise Ave. Manteca California 95337
B45 1119 W Middlesex Ave Bldg 4. Port Reading New Jersey 07064
B48 36445 Van Born Road, Suite 200 Romulus Michigan 48174
B49 42500 Winchester Rd. Temecula California 92590
B56 190 Medline Drive, Suite 200. Richmond Hill Georgia 31324
B66 2700 E. Imperial Highway Lynwood California 90262
B80 2341 Lauwiliwili St, Suite 107 Kapolei Hawaii 96707
B82 9103 Riverside Parkway Lithia Springs Georgia 30122
C02 2200 Cornerstone Parkway. Grayslake Illinois 60030
C03 1500 Medline Pl. McDonough Georgia 30253
C05 1062 Old Dixie Highway. Auburndale Florida 33823
C09 1960 W Miro Way. Rialto California 92376
C32 29895 US Hwy 90 Bus. Katy Texas 77494
C37 5000 Premier Parkway. St. Peters Missouri 63376
C40 81 Campanelli Dr. Uxbridge Massachusetts 01569
C41 1040 Enterprise Parkway South. West Jefferson Ohio 43162
C42 3446 Highway 51 N. Southaven Mississippi 38672
C46 5701 Promontory Parkway, Suite 100 Tracy California 95377
C47 239 Belvidere Rd. Perryville Maryland 21903
C50 8787 W Buckeye Ave. Tolleson Arizona 85353
C54 494 State Route 416. Montgomery New York 12549
C57 5511 W Ten Rd. Mebane North Carolina 27302
C59 2100 Industrial Park Road Hammond Louisiana 70401
C71 264 S 5750 W. Salt Lake City Utah 84104
C75 3770 Hogum Bay Rd NE. Lacey Washington 98516
C89 251 Hilton Dr. Jeffersonville Indiana 47130
RCH - Hartland, WI 700 W North Shore Dr. Hartland Wisconsin 53029
D46 - Lathrop, CA 18601 Christopher Way Ste 100. Lathrop California 95330
MXC - SPT 16415 Cosmos St. Moreno Valley California 92551
ANGIO 10 Glen Falls Technical Park. Glen Falls New York 12801
E22 600 Derby Ave West Haven Connecticut 06516
E23 3835 John Wall Dr Madison Wisconsin 53704

© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: CN101705524

LOC #: Chicago

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC.	Medline Industries, LP 3 Lakes Dr Northfield, IL 60093
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

E26 1390 Sparrows Point Blvd Ste700 Edgemere Maryland 21219
LRD 12001 General Milton Dr. Laredo Texas 78045

© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Medline Industries, LP MDEG License # (if applicable) _____

Physical Address 92 SE 223rd Ave.

City Gresham State OR Zip 97030

Mailing Address (if different from physical address) Three Lakes Drive - 3D

City Northfield State IL Zip 60093

Telephone 503-665-5824 Website www.medline.com

Licensing Company Email ralicensing@medline.com

Section 2: Personal Information

First Mark Middle Christopher Last Cardoos

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

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

Mailing Addres[redacted]

City Canby State OR Zip [redacted]

Telephone 503-665-5824 Email mcardoos@medline.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Riverside Community College		1989 - 1990	
Address	**City**	**State**	**Zip**
4800 Magnolia Ave.	Riverside	CA	92506
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Orange Coast College		1987 - 1989	
Address	**City**	**State**	**Zip**
2701 Fairview Road	Costa Mesa	CA	92628
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Yuba College		1986	
Address	**City**	**State**	**Zip**
2088 Magnolia Ave.	Marysville	CA	95901
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Lindhurst High School		09/83 - 06/86	
Address	**City**	**State**	**Zip**
4446 Olive Ave.	Olivehurst	CA	95961
Diploma/Degree obtained, if any			
High School Diploma			

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2014 - Present	[redacted]	Canby	OR	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Medline Industries, LP			11/09 - Present	
Business Address		**City**	**State**	**Zip**
92 SE 223rd Ave.		Gresham	OR	97030
Phone	**Title**		**Number of Employed Hours**	
503-665-5824	Director of Operations		33,000 +	
Description of Duties				
Oversee the facility to ensure proper receiving, distribution, storage, shipping and dispensing of prescription drugs and medical devices. Manage multiple team members to ensure proper record keeping, inventory, storage and product security.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

Mark Cardoos
Original Signature (electronic, copies or stamps not accepted)

7/8/2020
Date

I, Mark Cardoos, **certify that as the MDEG Administrator for**

Medline Industries, LP,

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

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

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

Mark, Cardoos
Print Name (First, Last)

Mark Cardoos
Original Signature (electronic, copies or stamps not accepted)

7/8/2026
Date

Board Use Only	Date Received: 8/17/26

Attachment 6

Medline - Gresham, OR - Employee List

First Name	Last Name	Primary Location
Randal	Russell	OPS- Gresham, OR B27
Nicholas	Mccoy	OPS- Gresham, OR B27
Irvin	Santos-ortega	OPS- Gresham, OR B27
Destynie	Blunt	OPS- Gresham, OR B27
Richard	Franks	OPS- Gresham, OR B27
Timothy	Ray	OPS- Gresham, OR B27
Robert	St Pierre	OPS- Gresham, OR B27
William	Dailey	OPS- Gresham, OR B27
Pheng	Xiong	OPS- Gresham, OR B27
Matthew	Norris	OPS- Gresham, OR B27
Jose	Reyes	OPS- Gresham, OR B27
Gavin	Shepherd	OPS- Gresham, OR B27
Saleh	Munassar	OPS- Gresham, OR B27
John	Stader	OPS- Gresham, OR B27
Timur	Ayupov	OPS- Gresham, OR B27
Delray	Price	OPS- Gresham, OR B27
Stephen	Lint	OPS- Gresham, OR B27
Timothy	Baker	OPS- Gresham, OR B27
Zachary	Hinkelman	OPS- Gresham, OR B27
Francisco	Torwan	OPS- Gresham, OR B27
Anthony	Marderosian	OPS- Gresham, OR B27
Zakaria	Safi	OPS- Gresham, OR B27
Sean	Fredrich	OPS- Gresham, OR B27
Dominic	Stephens	OPS- Gresham, OR B27
Christopher	Flynn	OPS- Gresham, OR B27
Victor	Varona Renteria	OPS- Gresham, OR B27
Nicholas	Pettis	OPS- Gresham, OR B27
Zac	Clow	OPS- Gresham, OR B27
Angel	Pineda-diaz	OPS- Gresham, OR B27
Chase	Belton	OPS- Gresham, OR B27
Jose	Morales-elias	OPS- Gresham, OR B27
Amanda	Littrell	OPS- Gresham, OR B27
Liam	Nelson	OPS- Gresham, OR B27
Colby	Madoka	OPS- Gresham, OR B27
Nolan	Beals	OPS- Gresham, OR B27
Tyler	Johnson	OPS- Gresham, OR B27
William	Squires	OPS- Gresham, OR B27
Lizet	Roman	OPS- Gresham, OR B27
Cindy	Vital	OPS- Gresham, OR B27
James	Movick	OPS- Gresham, OR B27
Andres	Vazquez-leon	OPS- Gresham, OR B27
Bailey	Davis	OPS- Gresham, OR B27
Martin	Liao	OPS- Gresham, OR B27
David	Carvajal Ortiz	OPS- Gresham, OR B27
Izaia	Medford-lewis	OPS- Gresham, OR B27
Charles	Narro	OPS- Gresham, OR B27
Michael	Stillwell	OPS- Gresham, OR B27
Isaiah	King	OPS- Gresham, OR B27
Josh	Clampitt	OPS- Gresham, OR B27

Gilmar	Saligan	OPS- Gresham, OR B27
Roy	Aguilar	OPS- Gresham, OR B27
Joshua	Stout	OPS- Gresham, OR B27
Alisa	Downard	OPS- Gresham, OR B27
Mohamed	Hamud	OPS- Gresham, OR B27
Ernesto	Sanchez	OPS- Gresham, OR B27
Weldon	Gaffney	OPS- Gresham, OR B27
Sherlyn	Romero	OPS- Gresham, OR B27
Thomas	Miles	OPS- Gresham, OR B27
Deandre	Woods	OPS- Gresham, OR B27
Christopher	Wilson	OPS- Gresham, OR B27
Matthew	Wood	OPS- Gresham, OR B27
Charlie	Navarro	OPS- Gresham, OR B27
Luis	Flores Huerta	OPS- Gresham, OR B27
Jeffrey	Fuller	OPS- Gresham, OR B27
Zakary	Coomer	OPS- Gresham, OR B27
David	Vera	OPS- Gresham, OR B27
Zabdiel	Elorza Salazar	OPS- Gresham, OR B27
Terry	Sion	OPS- Gresham, OR B27
Devonte	Smith	OPS- Gresham, OR B27
John	Johnson	OPS- Gresham, OR B27
Cristian	Vera Fuentes	OPS- Gresham, OR B27
Deven	Tooze	OPS- Gresham, OR B27
Issais	Guzman	OPS- Gresham, OR B27
Lizette	Vital	OPS- Gresham, OR B27
Jose	Andres-miguel	OPS- Gresham, OR B27
Jaxon	Morla	OPS- Gresham, OR B27
Johntavious	Geddis	OPS- Gresham, OR B27
Marquese	Bullard	OPS- Gresham, OR B27
Campbell	Dove	OPS- Gresham, OR B27
Timothy	Barron	OPS- Gresham, OR B27
Alberto	Tirado	OPS- Gresham, OR B27
Marquis	Silva	OPS- Gresham, OR B27
Sarah	Peck	OPS- Gresham, OR B27
Madison	Westerberg	OPS- Gresham, OR B27
Duran	Arguilez	OPS- Gresham, OR B27
Elizabeth	Allen	OPS- Gresham, OR B27
Thomas	Brown	OPS- Gresham, OR B27
Remi	Lopez	OPS- Gresham, OR B27
Chris	Heflen	OPS- Gresham, OR B27
Brandon	Isidoro	OPS- Gresham, OR B27
Shawn	Bosworth	OPS- Gresham, OR B27
Nathaniel	Trammel	OPS- Gresham, OR B27
Tracie	Miles	OPS- Gresham, OR B27
Cameron	Rogers	OPS- Gresham, OR B27
John	Henderson	OPS- Gresham, OR B27
Jakob	Bonillo	OPS- Gresham, OR B27
Sonny	Migliaccio	OPS- Gresham, OR B27
Antwaine	King	OPS- Gresham, OR B27
Edwin	Lindley	OPS- Gresham, OR B27
Haden	Burbank	OPS- Gresham, OR B27
Christopher	Muntz	OPS- Gresham, OR B27
Arthur	Teriong	OPS- Gresham, OR B27

Angel De Leon	Vianey Gracida	OPS- Gresham, OR B27
Allen	Johnson	OPS- Gresham, OR B27
Alyssa	Breum	OPS- Gresham, OR B27
Alyssa	Cox	OPS- Gresham, OR B27
Timothy	Mckenzie	OPS- Gresham, OR B27
James	Blunt	OPS- Gresham, OR B27
Christopher	Meyer	OPS- Gresham, OR B27
Von	Vang	OPS- Gresham, OR B27
Rickson	Sam	OPS- Gresham, OR B27
Bonnie	Fagle	OPS- Gresham, OR B27
Gunnar	Seay	OPS- Gresham, OR B27
Jenny	Herrejon Martinez	Gresham, OR B27
Carlos	Vargas Gallaga	Gresham, OR B27
Laura	Varona Renteria	OPS- Gresham, OR B27
Joe	Vongsay	OPS- Gresham, OR B27
Victor	Varona Renteria	Gresham, OR B27
Henry	Valkenaar	Gresham, OR B27
Victoria	Varona Renteria	OPS- Gresham, OR B27
Sarah	Ryan	OPS- Gresham, OR B27
Kisten	Hagan	OPS- Gresham, OR B27
Christian	Lozano	OPS- Gresham, OR B27
Ronald	Mitchell	Gresham, OR B27
Janeth	Servantes	Gresham, OR B27
Cipriano	Luna-sanchez	Gresham, OR B27
Antonio	Barker	OPS- Gresham, OR B27
Patrick	Kasenge	OPS- Gresham, OR B27
Dina	Hernandez De Smith	OPS- Gresham, OR B27
Chris	Price	OPS- Gresham, OR B27
Nathaniel	Powell	OPS- Gresham, OR B27
Kenneth	Lopez	Gresham, OR B27
Josue	Tafolla	Gresham, OR B27
Brian	Bailey	OPS- Gresham, OR B27
Nicholas	Welter	OPS- Gresham, OR B27
Roy	Aguilar	OPS- Gresham, OR B27
Han	Huynh	OPS- Gresham, OR B27
Mandy	Millar	Gresham, OR B27
Taylor	Sigler	OPS- Gresham, OR B27
Sean	Chojnacky	Gresham, OR B27
Nichole	Kidd	OPS- Gresham, OR B27
Yaritza	Rivera Carrillo	OPS- Gresham, OR B27
Michael	Barbosa-ceja	OPS- Gresham, OR B27
Peter	Giusto	Gresham, OR B27
Robert	Stephens	Gresham, OR B27
Jarred	Knisley	Gresham, OR B27
James	Robertson	Gresham, OR B27
Quency	Sadberry	OPS- Gresham, OR B27
Guy	Garrison	OPS- Gresham, OR B27
Erika	Diaz-palma	OPS- Gresham, OR B27
James	Mckenzie	OPS- Gresham, OR B27
Thomas	Simpson	OPS- Gresham, OR B27
Kevin	Strom	OPS- Gresham, OR B27
Ericka	Warnick	OPS- Gresham, OR B27
Maximilian	Viveros	OPS- Gresham, OR B27

Fernando	Zepeda Gonzalez	OPS- Gresham, OR B27
Cindy	Meyer	OPS- Gresham, OR B27
Cindy	Kavanagh	OPS- Gresham, OR B27
Daniel	Jyung	OPS- Gresham, OR B27
Greggory	Wilson-muldrow	OPS- Gresham, OR B27
Jason	Fisher	OPS- Gresham, OR B27
Katrina	Lindley	OPS- Gresham, OR B27
Krystal	Swan	OPS- Gresham, OR B27
Mark	Cardoos	OPS- Gresham, OR B27
Richard	Cowden	OPS- Gresham, OR B27
Sean	Norcross	OPS- Gresham, OR B27
Timothy	Cordier	OPS- Gresham, OR B27
Troy	Phipps	OPS- Gresham, OR B27
Tracy	Roufs	OPS- Gresham, OR B27
Vanessa	Torres	OPS- Gresham, OR B27
Varun	Damodarasamy	OPS- Gresham, OR B27
Wai	Yip	OPS- Gresham, OR B27

Attachment 5

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 001-43022

Medline Inc.

(Exact name of registrant as specified in its charter)

Delaware	**33-1845288**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3 Lakes Drive Northfield, Illinois	**60093**
(Address of principal executive offices)	(Zip Code)

(847) 949 5500
Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, par value $0.0001 per share	MDLN	Nasdaq Global Select Market

Securities registered pursuant to section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☐ No ☒

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ☐ No ☒

The aggregate market value of the Class A common stock held by non-affiliates of the registrant, based on the closing price of a share of Class A common stock on December 17, 2025, as reported by The Nasdaq Global Select Market on such date was approximately $13.0 billion. The registrant has elected to use December 17, 2025, which was the initial trading date of the registrant's Class A common stock on The Nasdaq Global Select Market, as the calculation date because on June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter) the registrant was a privately held company. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of February 23, 2026, there were 811,647,534 shares of the registrant's Class A common stock and 502,045,878 shares of the registrant's Class B common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement related to its 2026 Annual Meeting of Stockholders to be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year ended December 31, 2025 are incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

Item		Page
	PART I	
1.	Business	7
1A.	Risk Factors	22
1B.	Unresolved Staff Comments	55
1C.	Cybersecurity	55
2.	Properties	56
3.	Legal Proceedings	56
4.	Mine Safety Disclosures	57
	PART II	
5.	Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities	58
6.	[Reserved]	60
7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	61
7A.	Quantitative and Qualitative Disclosures About Market Risk	78
8.	Financial Statements and Supplementary Data	80
9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	135
9A.	Controls and Procedures	135
9B.	Other Information	135
9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	136
	PART III	
10.	Directors, Executive Officers, and Corporate Governance	136
11.	Executive Compensation	136
12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	136
13.	Certain Relationships and Related Transactions, and Director Independence	136
14.	Principal Accountant Fees and Services	136
	PART IV	
15.	Exhibits and Financial Statement Schedule	137
16.	Form 10-K Summary	142
	Signatures	143

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements include all statements that are not historical facts. Words such as "anticipate," "assume," "believe" "contemplate," "continue," "could," "estimate," "expect," "foreseeable," "intend," "may," "plan," "potentially," "predict," "project," "seek," "should," "will," or "would," or similar words or phrases that convey uncertainty of future events or outcomes, are intended to identify forward-looking statements in this Annual Report. These forward-looking statements relate to matters such as our industry, business strategy, costs, and costs savings, impacts of accounting standards and guidance, goals and expectations, market position, future operations, margins, profitability, capital expenditures, liquidity and capital resources, legal matters, trends, and other financial and operating information. The forward-looking statements are based on management's current expectations and are subject to various risks, uncertainty, and changes in circumstances, many of which are beyond our control, that could cause actual results to differ materially. Although we believe that the assumptions underlying the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance, or achievements. Factors that may cause actual results to differ from expected results include those described in Part I, "Item 1A—Risk Factors" and Part II, "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations". The forward-looking statements included in this Annual Report speak only as of the date of this Annual Report or as of the date they are made, as applicable. Except as otherwise required by law, we disclaim any intent or obligation to update any "forward-looking statement" made in this Annual Report to reflect changed assumptions, the occurrence of unanticipated events, or changes to future operating results over time.

INTRODUCTORY NOTE

Medline Inc. was incorporated as a Delaware corporation on November 6, 2024. Prior to the completion of its initial public offering (the "IPO") on December 18, 2025, Medline Inc. undertook certain reorganization transactions (the "Reorganization") such that Medline Inc. is now a holding company, and its sole material assets are its equity interests held directly or indirectly through wholly owned subsidiaries in Medline Holdings, LP ("Medline Holdings"). Following the IPO, Medline Holdings is the predecessor of Medline Inc. for financial reporting purposes. As the general partner of Medline Holdings, Medline Inc. now operates and controls all of the business and affairs of Medline Holdings and, through Medline Holdings and its subsidiaries, conducts its business. The Reorganization lacks economic substance and therefore is accounted for in a manner consistent with a reorganization of entities under common control. As a result, the consolidated financial statements of Medline Inc. recognize the assets and liabilities received in the Reorganization at their historical carrying amounts, as reflected in the historical financial statements of Medline Holdings. Medline Inc. will consolidate Medline Holdings on its consolidated financial statements and record a non-controlling interest related to the Units (as defined herein) held by the Continuing Unitholders (as defined herein) on its consolidated balance sheets and statements of comprehensive income.

Medline Inc. had no significant business transactions or activities prior to the Reorganization, and, as a result, the historical financial information reflects that of Medline Holdings.

Basis of Presentation

The consolidated financial statements and accompanying notes included herein are prepared in accordance with United States generally accepted accounting principles ("GAAP"). The results of businesses acquired or disposed of are included in the consolidated financial statements from the date of the acquisition or up to the date of disposal, respectively. All adjustments, in the opinion of management, necessary to a fair statement of the results for the annual periods presented have been made.

Certain monetary amounts, percentages, and other figures included in this Annual Report have been subject to rounding adjustments. Percentage amounts included in this Annual Report have been calculated, in some cases, not on the basis of such rounded figures, but on the basis of such amounts prior to rounding. For this reason, percentage amounts in this Annual Report may vary from those obtained by performing the same calculations using the figures, on the face of our consolidated financial statements included elsewhere in this Annual Report. Certain other amounts that appear in this Annual Report may not sum due to rounding.

In December 2024, we changed the name of Medline Holdings from Mozart Holdings, LP to Medline Holdings, LP. We will not distinguish between the prior and current name of Medline Holdings and will refer to the current name of Medline Holdings throughout this Annual Report. References in this Annual Report to "Medline," the "Company," "we," "us," and "our" refer (1) prior to the consummation of the IPO, to Medline Holdings, LP and its consolidated subsidiaries and (2) after the IPO to Medline Inc. and its consolidated subsidiaries.

CERTAIN DEFINITIONS

As used in this Annual Report, unless otherwise noted or the context requires otherwise, the following terms have the following meanings:

- "Class A Units" refers to the interests in Medline Holdings called "Class A Units" that were outstanding prior to the Reclassification. In connection with the Reclassification, (i) Class A Units held by Common Unitholders were converted into Common Units and (ii) Class A Units held by Exchanging Class A Unitholders were directly or indirectly exchanged for shares of Class A common stock.
- "Class B Units" refers to the interests in Medline Holdings called "Class B Units" that were outstanding prior to the Reclassification, and does not include CUPI Units. In connection with the Reclassification, (i) Class B Units held by Incentive Unitholders were converted into Incentive Units and (ii) Class B Units held by Exchanging Class B Unitholders were directly or indirectly exchanged for shares of Class A common stock (in the case of vested Class B Units) and/or restricted shares of Class A common stock (in the case of unvested Class B Units).

- "Common Units" refers to the new class of units of Medline Holdings created by the Reclassification and does not include Incentive Units.
- "Common Unitholders" refers to certain pre-IPO holders of Class A Units and/or CUPI Units who hold Common Units following the Reclassification.
- "Incentive Unitholders" refers to certain pre-IPO holders of Class B Units who will hold Incentive Units following the Reclassification, as described under "Organizational Structure."
- "Continuing Unitholders" refers collectively to Common Unitholders and Incentive Unitholders.
- "CUPI Units" refers to the interests in Medline Holdings that were designated as "Catch-Up Class B Units" and outstanding prior to the Reclassification. In connection with the Reclassification, (i) CUPI Units held by Common Unitholders were converted into Common Units and (ii) CUPI Units held by Exchanging CUPI Unitholders were directly or indirectly exchanged for shares of Class A common stock.
- "Designating Stockholder" refers to each of our Principal Stockholders with whom we entered into separate director nomination agreements.
- "Exchanging Class A Unitholder" refers to pre-IPO holders of Class A Units whose Class A Units were directly or indirectly exchanged for shares of Class A common stock following the Reclassification.
- "Exchanging Class B Unitholder" refers to pre-IPO holders of Class B Units whose Class B Units were directly or indirectly exchanged for shares of Class A common stock (in the case of vested Class B Units) and/or restricted shares of Class A common stock (in the case of unvested Class B Units) following the Reclassification.
- "Exchanging CUPI Unitholder" refers to pre-IPO holders of CUPI Units whose CUPI Units were directly or indirectly exchanged for shares of Class A common stock following the Reclassification.
- "Exchanging Unitholders" refers collectively to Exchanging Class A Unitholders, Exchanging CUPI Unitholders, and Exchanging Class B Unitholders.
- "Incentive Units" refers to the new class of units of Medline Holdings created by the reclassification of the Class B Units in the Reclassification. The Incentive Units are "profit interests" having economic characteristics similar to stock appreciation rights and having the right to share in any equity value of Medline Holdings above specified participation thresholds. Vested Incentive Units may be converted to Common Units and be subsequently exchanged for shares of Class A common stock.
- "Principal Stockholders" refers collectively to investment funds associated with Blackstone Inc., The Carlyle Group Inc. and Hellman & Friedman LLC, and members of the Mills family.
- "Reclassification" refers to the reclassification of the partnership interests of Medline Holdings prior to the IPO.
- "Sponsors" refers collectively to Blackstone Inc., The Carlyle Group Inc., and Hellman & Friedman LLC.
- "Units" refers collectively to Common Units and Incentive Units.

Summary of Risk Factors

The following is a summary of the principal factors that make an investment in our securities speculative or risky, all of which are more fully described below. This summary should be read together with the risk factors described under Part I, "Item 1A—Risk Factors" and should not be relied upon as an exhaustive summary of the material risks facing our business. In addition to the following summary, you should consider the information set forth below and the other information contained in this Annual Report before investing in our securities.

- Our global operations are subject to inherent risks that could materially adversely affect our business, results of operations, and financial condition.
- We may be unable to derive fully the anticipated benefits from our existing or future acquisitions, joint ventures, investments, dispositions, or other strategic transactions.
- Consolidation in the healthcare industry could have an adverse effect on our business, results of operations, and financial condition.
- We operate in a highly competitive industry, with accelerating pricing pressure and changes in technology.
- Changes to the U.S. and global healthcare environments may not be favorable to us.
- Increases in shipping costs or service issues with our third-party shippers could harm our business.

- Significant challenges or delays in our sourcing of new products and technologies could have an adverse impact on our long-term success.
- We have concentration in and dependence on certain healthcare provider customers and GPOs.
- Our business and operations depend on the proper functioning of our critical facilities and distribution networks and could be negatively impacted by events outside our control.
- Quality problems and product liability claims have in the past led, and could in the future lead, to recalls or safety alerts, reputational harm, adverse verdicts, or costly settlements, and could have a material adverse effect on our business, results of operations, and financial condition.
- Our failure to establish and maintain Prime Vendor relationships may cause our revenue to decline.
- If we experience increased pressure to maintain or decrease the price of our goods and services and we are unable to reduce our expenses, there may be a material adverse effect on our business, results of operations, and financial condition.
- Any failure by or loss of a third-party manufacturer or supplier or other manufacturing or supply-related impacts could result in delays and increased costs, which may adversely affect our business.
- We rely on the proper function, security, and availability of our information technology systems and data, as well as those of third parties throughout our global supply chain, to operate our business.
- We are subject to extensive and complex laws and governmental regulations and any adverse regulatory action may materially adversely affect our business, results of operations, and financial condition both inside and outside the United States.
- We are subject to complex and rapidly evolving data privacy, security, and data protection laws and regulations and the costs to comply with such laws and regulations or any ineffective compliance efforts with such laws and regulations may adversely impact our business.
- Our use or our third-party service providers' or business partners' use of AI, automated decision-making and machine learning technologies and the evolving regulatory framework in this area may subject us to risks or heightened costs that could adversely affect business, results of operation and financial condition.
- Our failure to comply with laws and regulations relating to reimbursement of healthcare goods and services may subject us to penalties and adversely impact our reputation, business, results of operations, financial condition, and cash flows.
- Uncertain global and domestic macro-economic and political conditions could materially adversely affect our business, results of operations, and financial condition.
- Our substantial indebtedness could adversely affect our financial condition, our ability to operate our business or react to changes in the economy or our industry, prevent us from fulfilling our obligations under our debts, and divert our cash flow from operations for debt payments.
- The credit agreement that governs the Senior Secured Credit Facilities and the indentures that govern the Senior Notes will each impose significant operating and financial restrictions on our subsidiaries, which may prevent us from capitalizing on business opportunities.
- Medline Inc. is a holding company and its only material assets are its equity interests held directly or indirectly through wholly owned subsidiaries in Medline Holdings, and it is accordingly dependent upon distributions from Medline Holdings to pay taxes, make payments under the tax receivable agreement, and pay any dividends.
- The Designating Stockholders hold a significant percentage of our stock, and their interests may conflict with ours or yours in the future.
- Our amended and restated certificate of incorporation does not limit the ability of our Sponsors, the Mills family, and certain other pre-IPO investors to compete with us, and they may have investments in businesses whose interests conflict with ours.

The market price of shares of our Class A common stock may be volatile or may decline regardless of our operating performance, which could cause the value of your investment to decline.

Market and Industry Data

Unless otherwise indicated, information contained in this Annual Report concerning our industry, competitive position, and the markets in which we operate is based on information from independent industry and research organizations, other third-party sources and management estimates. Although we believe that these third-party sources are reliable, we do not guarantee the accuracy or completeness of this information, and we have not independently verified this information. Management estimates are derived from information obtained from surveys, reports by market research firms, our customers, distributors, suppliers, trade and business organizations, and other contacts in the markets in which we operate and have not been verified by independent sources, and are based on assumptions made by us upon reviewing such data, and our experience in, and knowledge of, such industry and markets, which we believe to be reasonable. In addition, assumptions and estimates of our and our industry's future performance are subject to a high degree of uncertainty and risk due to a variety of factors, including those described in Part I, "Item 1A—Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

Statements regarding our market position (including statements that we are the largest company in a particular market), unless otherwise noted, are based on our 2025 net sales in the relevant market relative to the publicly reported net sales of our competitors in such market, including with respect to our statement of being the largest provider of med-surg products and supply chain solutions serving all points of care, as that statement is based on our 2025 net sales relative to the publicly reported net sales of med-surg products by companies that are both med-surg manufacturers and distributors.

Trademarks

We own or have the right to use trademarks, trade names, and service marks used in connection with our business, including, but not limited to, Medline, Curad, Microtek, Hudson, and Proxima. All trademarks, trade names, and service marks referred to in this Annual Report are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks, or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies. Solely for convenience, our trademarks, trade names, and service marks referred to in this Annual Report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names, and service marks.

PART I

Item 1. Business

General

Medline Inc. (together with its subsidiaries, "Medline", "the Company", "we", "ours" and "us") is the largest provider of medical-surgical ("med-surg") products and supply chain solutions serving all points of care, based on total net sales of med-surg products. Medline was founded in 1966 and today delivers mission-critical products used daily across the full range of care settings, from hospitals and surgery centers to physician offices and post-acute facilities. Our mission is to make healthcare run better by delivering improved clinical, financial, and operational outcomes.

We have two reportable segments, Medline Brand and Supply Chain Solutions, the combination of which addresses critical needs in the market through a comprehensive solution. They are both supported by our Prime Vendor model, differentiated distribution network, and robust commercial platform. Through our two segments, we offer approximately 335,000 med-surg products, including surgical and procedural kits, gloves and protective apparel, urological and incontinence care, wound care, and consumable lab and diagnostics products. We distribute these products through our expansive network of global distribution facilities and our owned fleet of MedTrans trucks.

Medline Brand

As of December 31, 2025, we offer our customers approximately 190,000 med-surg products through our Medline Brand segment and hold leading positions across many key product families for our Medline Brand products. Our Medline Brand products are organized into three product categories: Front Line Care, Surgical Solutions, and Laboratory and Diagnostics.

- *Front Line Care* offers mission-critical med-surg products for patient-facing needs, including wound care products, exam gloves, skin care and incontinence products, environment cleaning supplies, textiles, hand sanitizer, durable medical equipment, patient plastics, and decolonization and infection control products.
- *Surgical Solutions* offers operating room and perioperative environment product solutions, including surgical procedure trays, drapes and gowns, personal protective equipment, sterile wraps, surgical instruments, surgeon's gloves, procedure kits, and orthopedic implants.
- *Laboratory and Diagnostics* offers a full range of laboratory and diagnostic product solutions, including point of care testing, analyzers and instrumentation, lab and diagnostic consumables, diagnostic instruments, vital signs monitors, and anatomic pathology and phlebotomy products.

Our product development approach incorporates customer feedback and ongoing innovation. We are also committed to delivering products of the highest standard, which is reflected by our robust quality team embedded across our manufacturing and sourcing locations. The expertise of our research and development team and quality team helps ensure products bearing the Medline brand meet both our rigorous quality standards and our customers' expectations.

Supply Chain Solutions

As of December 31, 2025, we offer approximately 145,000 med-surg products from over 1,300 third-party suppliers, including nearly all leading national brands, through our Supply Chain Solutions segment. We also provide our customers with supply chain optimization services such as consulting engagements, outsourced warehouse and technology management, put-away-ready packaging, third-party logistics, inventory rationalization, and route planning. Our third-party suppliers are primarily responsible for costs related to import and inbound freight, whereas we are primarily responsible for costs related to outbound freight from our distribution centers. Our supply chain expertise allows us to provide additional service offerings to optimize our customers' supply chain and inventory workflows, helping these customers cost-effectively manage their supply chain while building strong relationships and enhancing retention.

Our Prime Vendor Model

A Prime Vendor relationship is a relationship for which there is a multi-year distribution agreement between Medline and a customer, whereby the customer agrees to use Medline for the vast majority of its med-surg product needs.

In our Prime Vendor relationships, we enter into long-term agreements, typically structured with five-year terms, to act as the primary consolidated logistics partner for these customers' med-surg product needs. These agreements have been and are expected to continue to be a key contributor to our growth. Our customers realize efficiencies by partnering with one supply chain partner to consolidate their med-surg purchase volume. Prior to the market adoption of the Prime Vendor model, customers sourced such products individually from a highly fragmented base of suppliers. The Prime Vendor model instead centralizes procurement and distribution, which in turn drives efficiency and higher service levels.

As Prime Vendor, we drive significant cost savings to our customers. Our scale allows us to deliver consistently lower prices and better service levels on Medline Brand products relative to third-party alternatives, while also lowering the distribution cost for delivery of the full range of med-surg products. This often motivates customers to purchase more Medline Brand products over time. The opportunity is even greater in certain non-acute settings, where we sell a more focused product portfolio. Our Prime Vendor model allows us to provide cost savings to Prime Vendor customers, which, over time, supports incremental purchasing of our Medline Brand products and greater scale across our operations. As our scale grows, we are able to realize further efficiencies by offering superior or similar quality to third-party products at a more cost-effective price. We believe that Medline Brand conversion is mutually beneficial for both our customers and us-the value we provide customers at the outset of a Prime Vendor agreement meaningfully increases over time, as they accrue savings by purchasing our lower cost Medline Brand products, while our profitability grows given the enhanced margin profile of Medline Brand products. This compelling value proposition and supply chain relationship with our customers supports our greater than 98% average Prime Vendor retention rate over the past five years.

A portion of Supply Chain Solutions products sold to existing Prime Vendor customers has like-for-like Medline Brand product equivalents, representing a potential gross profit uplift consistent with our historical margin differentials if such products were converted for Medline Brand products. While we historically have earned higher margins upon conversion from third-party national brand products to like-for-like Medline Brand products, because of the lower average prices for Medline Brand products, there is typically a negative impact on net sales upon the conversion of Supply Chain Solutions products to like-for-like Medline Brand products if volume is assumed to be constant. For additional information on potential risks relating to this conversion opportunity, please see Part I, "Item 1A—Risk Factors—Risks Related to Our Business, Industry and Operations—Our failure to establish and maintain Prime Vendor relationships may cause our revenue to decline."

Our Distribution Network

We have a differentiated distribution network of 70 global distribution centers, warehouses, cross-docks, and transship facilities, 45 of which are in the United States, strategically located to provide next-day delivery to 95% of our U.S. customer base. We utilize artificial intelligence ("AI") and robotics technology in over 26 million square feet of warehouse space in the United States to improve efficiency and capacity to optimize distribution logistics and maximize utilization. The products we distribute are packaged to meet each customer's individual needs and to be "put-away-ready," which streamlines the customer's unloading and shelving process. We also operate our own fleet of more than 2,100 MedTrans trucks that deliver our products across care settings within the United States. As of December 31, 2025, we had approximately 25% in incremental capacity across our platform to support our long-term growth.

Our Commercial Platform

Our deep connectivity to our customers is driven by the strength of our dedicated and tenured commercial team. We have a U.S. commercial team of approximately 4,000 people across all points of care, which includes account managers, product specialists, specialized clinical resources, customer service representatives, supply chain specialists, Prime Vendor analysts, and a robust leadership team dedicated to driving efficiencies for our customers through their teams. We have created an entrepreneurial environment that empowers our salesforce to work with our product managers to create innovative products that meet market demand. We have a team devoted to each channel in the United States and each region or country internationally, which allows our salesforce teams to develop market-specific knowledge.

Research and Development

We have a track record of successfully bringing new products to market, with more than 2,300 granted patents and more than 450 U.S. Food and Drug Administration ("FDA") 510(k) clearances. Over the last three years, we have successfully launched more than 250 new products.

Competition

Our value proposition is derived from our integrated business model, the breadth of our Medline Brand portfolio, our differentiated supply chain, and the overall quality and cost of our products. As a result of our integrated business model, our competitors include both other leading med-surg product manufacturers and distributors.

Similar to us, other leading med-surg product manufacturers produce a wide range of med-surg supplies. However, unlike us, many of these competitors are reliant upon third-party distributors to deliver their products to customers. By nature of being a distributor, Medline has direct access to and manages the end customer relationships. This enables us to offer a complete solution as a manufacturer and a distributor, offering our customers what we believe to be best-in-class supply chain logistics, and driving value through our brand.

Additionally, other distributors of med-surg products similarly connect the fragmented supplier and provider bases and aggregate inventory from suppliers to deliver products to customers, such as McKesson, Cardinal Health, Owens & Minor, and Henry Schein. These distribution companies compete with us for Prime Vendor agreements. However, we believe that many of these competitors do not benefit from the scale and scope of our vertical integration or commercial excellence, and thus are not able to provide the same magnitude of cost savings, value, and holistic solutions that we deliver for our customers.

Production and Raw Materials

We manufacture approximately one-third of our Medline Brand products, which are primarily Class I and II medical devices, through our 30 manufacturing facilities, of which 24 are in North America. We purchase many of the components and raw materials used in manufacturing our products from numerous suppliers. We focus our manufacturing capabilities on products where we can leverage technology and automation to drive higher quality and lower costs to better serve our customers. For the vast majority of the other two-thirds of our Medline Brand products, we work closely with our network of more than 600 global partners across approximately 40 countries, many of whom have decades-long exclusive relationships with us. The breadth of our global sourcing partnerships provides diversification and strengthens our resiliency, with no single sourcing partner accounting for more than 5% of total spend as of December 31, 2025.

We also have plans and measures in place to help ensure continuity of supply while maintaining high quality and reliability. Generally, we have been able to obtain adequate supplies of such raw materials and components. However, due to the FDA's manufacturing requirements and those of other regulatory authorities, we may not be able to quickly establish additional or replacement sources for certain components, materials or processes if we experience a sudden or unexpected reduction or interruption in supply or services and are unable to develop alternative sources.

Human Capital Resources

At Medline, our relentless focus on the customer drives our human capital strategy, which revolves around attracting, developing, and retaining employees to provide the best products and services for our customers. We have developed a strong foundation that drives our recruitment, retention and development efforts. We are committed to supporting the personal and professional development of our employees, as well as providing competitive benefits and a safe, inclusive workplace.

As of December 31, 2025, we employed over 45,000 employees worldwide, with over 26,000 located in the United States. Our largest non-U.S. employee populations are in Mexico, Dominican Republic, India, Canada, Slovakia, France, China, Japan, Germany, and Australia. None of our employees in the United States are unionized, though some of our employees in Mexico belong to unions. In Germany and the Netherlands, employees are represented through Works Councils; in France and Spain, employees are represented through both Works Councils and industry-wide collective bargaining agreements; and in Belgium and Italy, employees are also represented through industry-wide collective bargaining agreements. In Australia, certain employees are represented by an enterprise bargaining agreement; in Japan, employees are represented through a Work Council; and in Vietnam, employees are represented through a collective bargaining agreement. We believe that our positive employee relations and total employee experience drive the continual growth of our workforce.

Culture and Values

Our culture is grounded in a customer-focused, collaborative, and performance-driven approach, guided by core values emphasizing relentless customer focus, agility and flexibility, problem-solving, drive to succeed, purposeful candor, and the importance of relationships. Employees are encouraged to exercise judgment, work transparently with customers, and contribute meaningfully to our mission to make healthcare run better.

Talent Attraction and Development

We seek to attract employees whose skills, experience, and motivation align with our operational and technical needs. Through continual improvement of internal processes, an awareness of market and candidate driven trends, and in partnership with vendors and other outside organizations, our talent acquisition programs focus on efficient hiring processes, market awareness, and building a diverse pipeline of candidates. We support development through consistent performance management processes and early career opportunities to take on additional responsibilities to demonstrate their competencies and drive to succeed and on-the-job responsibility augmented by formal training and development to refine technical and leadership skills. New sales representatives participate in comprehensive training programs, and product managers have targeted development pathways through all stages of their careers, from mandatory onboarding offerings to advanced classes that provide the necessary skills with increasing levels of responsibility, to support progression over time.

Employee Engagement and Inclusion

We believe our employees' ability to communicate and cooperate effectively across functional and departmental teams positively impacts our performance. We engage in various listening strategies and foster engagement through survey feedback mechanisms, anonymous employee feedback platform, focus groups, increased attention to onboarding and offboarding feedback, pulse surveys on remote work needs, and other listening strategies. Insights from these efforts inform workplace improvements. We also support an inclusive environment through Employee Resource Groups and leadership training initiatives designed to reduce bias in talent decisions and strengthen representation across the company.

Health, Safety, and Well-Being

We are committed to maintaining a safe workplace and supporting the physical, emotional, and financial well-being of our employees. We provide competitive health and benefits programs, access to assistance resources where available, and opportunities for community involvement through charitable giving, including financial giving and in-kind giving such as product donations.

Intellectual Property

We rely upon patents, trademarks, copyrights, trade secrets and other intellectual property rights to maintain and improve our competitive position. We have a large portfolio of intellectual property, including more than 2,300 granted patents as well as trademark registrations protecting our notable brands, including Medline, Curad, Microtek, Hudson, and Proxima.

We consider the trademarks and know-how that we own to be material to our business. However, other than the Medline mark, we do not consider our business to be materially dependent upon any individual trademark registration or trade secret. In the aggregate, we consider our more than 2,300 granted patents to be material to our business. However, no single patent or group of related patents is material to our business as a whole or any segment of our business.

We believe that we have taken all necessary steps to protect our intellectual property rights, but no assurance can be given that we will be able to successfully enforce or protect our rights in the event that they are infringed upon or challenged by a third party. See Part I, "Item 1A —Risk Factors—Risks Related to Regulation and Legal Proceedings—Any failure to obtain, maintain, protect and enforce our intellectual property rights, or the failure of the strength or scope of our intellectual property rights, could harm our business, financial condition, and results of operations" and "—Risks Related to Regulation and Legal Proceedings—We may become subject to litigation brought by third parties claiming infringement, misappropriation, or other violation by us of their intellectual property rights."

Government Regulation

Our operations and products are subject to extensive regulation by numerous governmental regulatory authorities, including U.S. and other international regulatory authorities, and other government agencies inside and outside the United States. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, design, materials, testing, safety, efficacy, quality, purity, manufacturing, methods, controls, testing, screening, recordkeeping, reporting, processing, storage, registration, authorization, licensing, permitting, labeling, advertising, marketing, distribution, offer for sale, sale, use, expiration, pricing, reimbursement, import, export, clinical trials, post-marketing surveillance of our products, the registration of our facilities, and the claims that we make about our products. The United States and other countries where we sell healthcare and other regulated products, including drugs, human cell and tissue products, dietary supplements, cosmetics, certain foods, and consumer products subject such products to their own clearance, authorization, approval, registration, listing, labeling, manufacturing, recordkeeping, reporting, and other regulatory requirements regarding the performance, safety, and quality of such products. We are also subject to healthcare and other regulations and enforcement by the federal government and the states and foreign governments and authorities in the locations in which we conduct our business. The U.S. governmental and regulatory authorities that enforce such laws and rules, and that issue guidance on compliance with such laws and rules include, without limitation, the FDA, the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the U.S. Department of Health and Human Services ("HHS"), the HHS Office of Inspector General, U.S. Environmental Protection Agency ("EPA"), the Federal Trade Commission ("the FTC"), Consumer Product Safety Commission ("CPSC"), the U.S. Department of Justice ("DOJ") and individual U.S. Attorney offices within the DOJ, as well as state and local governments. Our business is also affected by patient and data privacy and security laws, government payer cost containment initiatives, government reimbursement laws and regulations, environmental, health, and safety laws and regulations, as well as laws and regulations with respect to the sale, transportation, storage, handling, and disposal of hazardous or potentially hazardous substances, and safe working conditions. Our business also maintains contracts with governmental agencies and such contracts are subject to various government procurement laws and regulations, required contract provisions, and other requirements relating to contract formation, administration and performance. Failure to comply with applicable laws and regulations or with contractual or other requirements may result in monetary damages and criminal or civil penalties as well as termination of our government contracts or our suspension or debarment from government contract work.

The regulations to which we are subject are complex and have tended to become more stringent over time. If our business expands in certain ways, including through the offering of new products and services or entering into new geographic areas, we may be subject to new and additional regulatory requirements. The foreign, federal, state, and local regulatory authorities have broad inspection and enforcement powers, including the ability to suspend or limit the distribution of products, suspend, revoke, or terminate our product and facility licenses, permits, and authorizations, request the cessation of distribution and shipments of certain products due to regulatory, safety, or other issues, seize or order the recall of our products, issue safety, quality, or other communications to the public or healthcare providers, enforce laws related to marketing, including promotion of off-label uses of products, and impose injunctions and significant criminal, civil, and administrative sanctions for violations of laws and regulations. Any adverse regulatory or other action, including any adverse press releases or other communications from regulators, may impact our business practices and operations, including by limiting our ability to effectively market, ship, and sell our products, affecting the production and distribution of products by our manufacturing facilities, subjecting us to significant liability, and limiting our ability to obtain future authorizations. Although we are subject to international government regulations in the international end markets where we operate and/or provide our products, these regulations do not have a material impact on our products as no international market represents more than 3% of our net sales.

Government Regulation of Medical Devices

Our medical devices are subject to regulation by numerous government agencies, including the FDA and comparable state and foreign agencies. Regulations of the FDA and other regulatory agencies in and outside the United States impose extensive compliance and monitoring obligations on portions of our business. The FDA and other U.S. and foreign governmental agencies regulate, among other things, with respect to medical devices: design, development, and manufacturing; testing, registration, listing, labeling, content, and language of instructions for use and storage; clinical trials; product safety; marketing, sales, and distribution; licensing and permit requirements; premarket clearance, approval and authorization; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval studies; and product import and export. The regulations to which we are subject are complex and have tended to become more stringent over time. If our business expands in certain ways, we may be subject to new and additional regulatory requirements. The FDA and state regulatory authorities have broad inspection and enforcement powers, including the ability to suspend or limit the distribution of products by our distribution centers; seize or order the recall of products; terminate, suspend, or revoke licenses and permits; and impose significant criminal, civil, and administrative sanctions for violations of these laws and regulations. Foreign regulations subject us to similar foreign enforcement powers. In addition, the FDA and other governmental and regulatory authorities, both in and outside the United States (including the FTC, the HHS Office of the Inspector General, the DOJ, and various state Attorneys General), monitor the promotion and advertising of our products. Any adverse regulatory or other action, including any adverse press releases or other communications from regulators, depending on its magnitude, may limit our ability to effectively market, ship, and sell our products, limit our ability to obtain future premarket authorizations, or result in a substantial modification to our business practices and operations.

FDA Premarket Clearance and Approval Requirements

Each medical device we wish to distribute commercially in the United States requires marketing authorization from the FDA prior to distribution, unless the device is exempt from premarket notification requirements. The type of marketing authorization necessary is generally linked to the classification of the device. The FDA classifies medical devices into one of three classes-Class I, II, or III-based on the degree of risk associated with a device and the level of regulatory control deemed necessary to ensure its safety and effectiveness. Class I devices that pose the least risk are subject only to General Controls applicable to all devices, such as requirements for device labeling, premarket notification, and adherence to current good manufacturing practices for devices as set forth in the Quality System Regulation ("QSR"). Class II devices that pose a moderate risk are subject to General Controls and may also be subject to Special Controls, such as performance standards, product-specific guidance documents, special labeling requirements, patient registries, or post-market surveillance. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through General and Special Controls, including devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential unreasonable risk of illness or injury.

Most Class I devices and some Class II devices are exempted by regulation from the 510(k) clearance requirement and can be marketed without prior authorization from the FDA. Class I and II devices that are not exempted are eligible for marketing through the 510(k) clearance pathway. By contrast, devices placed in Class III generally require premarket approval ("PMA") or de novo clearance prior to commercial marketing. The PMA approval process is more stringent, time-consuming and expensive than the 510(k) clearance process; however, the 510(k) clearance process has also become increasingly stringent and expensive. None of our products are currently approved under a PMA, and we have no plans for any indication or system improvement or extension that we believe would require a PMA. If, in the future, we were to file a PMA, we may be subject to additional regulatory requirements.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

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

Provide explanation below:

*See Attachment 1 - Corporate Disciplinary History

Previously Reviewed & Approved

Original Signature (electronic, copies or stamps not accepted)

08/10/26
Date

Attachment 1

Medline Industries, LP- Discipline *Confidential*

Date of Resolution	Facility	Description
08/03/2005	1401 N. Universal Ave Kansas City, MO 64120	**Case:** 2003031660 **Agency:** Missouri Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement, 5 years' probation **Summary:** Medline Industries Inc. distribution center at 1401 N. Universal Ave, Kansas City, MO 64120 (MO# DD2003031660) cited for failure to renew on time and deficient temperature control procedures. All issues resolved via Settlement Agreement effective 08/03/2005. License placed on probation for 5 years. The state conducted multiple inspections of the facility throughout the probationary period and found Medline to comply with all requirements. The probationary period closed in August 2010. **Corrective Actions:** Medline hired additional staff to monitor and ensure on-time license renewal. A temperature control room was constructed at the facility to ensure products are stored at the appropriate temperature and humidity.
12/07/2006	9101 Riverside Pkwy Lithia Springs, GA 30122	**Case:** N/A **Agency:** Florida Department of Health **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Temporary Suspension Lifted **Summary:** Medline Industries Inc. distribution center at 9101 Riverside Pkwy Lithia Springs, GA 30122 Non-Resident FL Permit (FL # 23:1470) suspended for operating without a FL Certified Designated Representative. The CDR resigned unexpectedly. Upon receipt of the notice of intent to suspend, Medline stopped all shipments into the state of FL. Permit was reinstated upon hiring of a new licensed Florida CDR. **Corrective Actions:** Qualified FL Certified Designated Representative hired for facility. Medline implemented a policy requiring all FL licensed distribution centers to maintain a backup Florida Certified Designated Representative on staff.
02/08/2008	2708 NE Waldo Rd. Gainesville, FL 32609	**Case:** 2007-37412 **Agency:** Florida Department of Health **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement **Summary:** Medline Industries, Inc. distribution center at 2708 NE Waldo Rd., Gainesville, FL 32609 FL Permit (FL # 22:1022) suspended for violations identified during a Florida BOP facility inspection. Medline, through Counsel, addressed the issues raised in the inspection and established that the suspension was unjustified. The suspension was lifted 3 days later on January 22, 2008. Medline Industries, Inc. entered into a settlement agreement on 02/08/2008 with the FL Department of Health to resolve all issues related to the case. **Corrective Actions:** Medline conducted a thorough review of its policies and procedures and implemented an internal auditing program to ensure that all distribution centers comply with internal policies and procedures and state and federal regulations.
05/01/2008	149 New Camellia Blvd. Covington, LA 70433	**Case:** 2008006 **Agency:** Louisiana Board of Wholesale Drug Distributors **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Consent Decree **Summary:** Medline Industries Inc. distribution center at 149 New Camellia Blvd. Covington, LA 70433 (LA #4318) cited for failure to properly maintain copies of current customer licenses on-site. Licenses were maintained by Medline's Regulatory team at corporate headquarters. Medline entered a consent decree effective 05/01/2008 to resolve the alleged violation. **Corrective Actions:** Medline implemented digital storage of customer licenses to allow for on-demand access by distribution centers.

Medline Industries, LP- Discipline *Confidential*

07/08/2008	94-1420 Moaniani St. Waipahu, HI 96797	**Case #:** PHA 2008-71-L **Agency:** Hawaii Department of Commerce and Consumer Affairs **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, Inc. distribution center at 94-1420 Moaniani St., Waipahu, HI 96797 (HI # PWD 115) entered a settlement agreement and placed on probation for 5 years for failure to report disciplinary actions within 30 days. Medline submitted all required notices but missed the 30-day deadline. The probationary period ended in August 2013. **Corrective Actions:** Medline implemented a policy and procedure to notify licensing boards of disciplinary actions within the required reporting timelines.
09/06/2008	10601 Southport Dr. Orlando, FL 32824 401 Commerce Blvd. Oldsmar, FL 34677 4750 118th Ave N Clearwater, FL 33762	**Case #:** 2007-11783; 2007-36555; 2007-38894; 2007-38895; 2007-38896; 2007-39073; 2008-02011; 2008-11215 **Agency:** Florida Department of Health **Entity:** Medline Industries, Inc.; Medline Manufacturing & Services, LLC **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries Inc. and Medline Manufacturing & Services, LLC was cited for several violations related to distribution centers in Florida, including, failure to pass and maintain a Florida compliant pedigree, maintaining the wrong permit type for the activities performed (Florida required a repackager permit in addition to the existing manufacturer permit), distribution of saline to an unauthorized recipient, and storage of a prescription drug in an unlicensed raw materials storage facility. Medline challenged several violations, resulting in most being substantially reduced or removed. All issues were addressed and resolved to the satisfaction of the FL DOH. A settlement agreement was reached to resolve all matters and approved on 09/06/2008. **Corrective Actions** Medline instituted a Florida specific pedigree system to address the pedigree issues. The updated pedigree ensures that all applicable shipments to Florida have the required Florida documentation and comply with FL pedigree requirements (Note - these requirements have since been preempted by the federal Drug Supply Chain Security Act). Medline secured the repackaging permit to address the missing permit type. Medline instituted a new procedure for obtaining and maintaining customer licenses for all prescription drug purchases- this procedure generates an automatic block for any prescription drug order by an unlicensed customer. The prescription drug item unintentionally stored in the raw materials facility was properly disposed of and waste disposal procedures updated to prevent this from occurring in the future.
02/04/2009	5450 W. Stewart Ave. Wausau, WI 54401	**Case:** 08 PHM 037 **Agency:** Wisconsin Department of Regulation and Licensing **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Stipulation Order **Summary:** Medline Industries Inc. distribution center at 5450 W. Stewart Ave., Wausau, WI 54401 (WI # 1116-045) cited for missing policies and procedures and storage of drugs in a non-secure location following an inspection by the Wisconsin Department of Regulation & Licensing. Medline managed a portion of a Wisconsin hospital's warehouse. The inspector cited Medline for failure to install a dividing fence between the Medline warehouse and the hospital portion of the facility. All hospital products were owned by the hospital. Medline was also cited for failure to access policies and procedures during the inspection. Corrections were made and the facility re-inspected, to the satisfaction of the state. Medline entered a stipulation order effective 02/04/2009 to resolve the matter. **Corrective Actions:** Medline installed a locked fence to separate the hospital's owned products. Medline also completed a review of all facilities to ensure proper separation of products. On-site staff provided additional training on how to access current policies and procedures during an inspection.

Medline Industries, LP- Discipline *Confidential*

05/19/2009	94-1420 Moaniani St. Waipahu, HI 96797	**Case:** PHA 2009-7-L **Agency:** Hawaii Department of Commerce and Consumer Affairs **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, Inc. agreed to enter a Consent Order for discipline incurred in another jurisdiction (Wisconsin Case #: 08 PHM 037). **Corrective Actions:** See Corrective Actions for Case #: 08 PHM 037.
03/19/2010	1401 N. Universal Ave. Kansas City, MO 64120	**Case:** 2010-002994 **Agency:** Colorado State Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Stipulation **Summary:** Medline Industries, Inc. distribution center at 1401 N. Universal Ave, Kansas City, MO 64120 applied for a Colorado Out-of-State Wholesaler license. The CO Board of Pharmacy issued a conditional license until the facility's MO probation period ended. (See Case 2003031660 above). Medline informed the CO Board when the MO probationary period was completed. Upon completion of probation, the Board issued a full license. **Corrective Actions:** Medline successfully completed terms of probation in MO and CO.
07/18/2014	3301 Route 6 Middletown, NY 10940	**Case:** 27278 **Agency:** NY State Education Department- Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Consent Order **Summary:** Medline Industries, Inc. agreed to enter a Consent Order for discipline incurred in another jurisdiction (FL No. 2007-37412, LA No. 2008006, and WI No. 08 PHM 037). **Corrective Actions:** See corrective actions for FL No. 2007-37412, LA No. 2008006, and WI No. 08 PHM 037.
01/06/2021	1501 Harris Rd Libertyville, IL 60048	**Case:** A-2020-0054 **Agency:** Ohio Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, Inc. distribution center at 1501 Harris Rd Libertyville, IL 60048 (OH License #01-1985050) entered into a settlement agreement with the Ohio Board of Pharmacy for the sale of dangerous drugs to an unlicensed entity. Medline maintained a current and valid DEA license on file rather than the correct Terminal Distributor Dangerous Drugs license (TDDD). The facility's TDDD license expired at the time of the sale. Case resolved via Settlement Agreement effective 01/06/2021. **Corrective Actions:** Medline updated its customer license requirements for Ohio customers. Medline completed a review of all Ohio customers to verify the correct license type was on file and implemented increased verification checks of Ohio licenses.

Medline Industries, LP- Discipline *Confidential*

06/28/2021	1501 Harris Rd Libertyville, IL 60048	**Case:** 21-L-0048 **Agency:** Alabama Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Order **Summary:** Medline Industries, Inc. distribution center at 1501 Harris Rd Libertyville, IL 60048 (AL Non-Resident Permit #193718) was fined for discipline incurred in another jurisdiction (OH A-2020-0054) **Corrective Actions:** See corrective action for OH A-2020-0054.
11/01/2022	1040 Enterprise Parkway South West Jefferson, OH 43162	**Case:** A-2022-0333 **Agency:** Ohio Board of Pharmacy **Entity:** Medline Industries, LP **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, LP distribution center at 1040 Enterprise Parkway South, West Jefferson, OH 43162 (OH License #01-30000190) entered a settlement agreement with the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file instead of the correct Terminal Distributor Dangerous Drugs license (TDDD). The TDDD license was added in May 2022. During the period of July 2021 to March 2022, the customer's TDDD license lapsed, and Medline shipped the customer product under the valid practitioner license. Case resolved via Settlement Agreement effective 11/01/2022. **Corrective Actions:** Medline updated customer licensing requirements for Ohio customers following OH Case # A-2020-0054. The shipments in this matter occurred while Medline was in the process of reviewing and updating all Ohio customer licenses. Medline licensing staff were also provided with additional training on Ohio license requirements.
12/19/2022	9670 NW 112th Ave Miami, FL 33178	**Case:** 2022-031132 **Agency:** FL Dept. Business and Professional Regulation, Div. of Drugs, Devices, and Cosmetics **Entity:** Medline Industries, LP **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, LP distribution center at 9670 NW 112th Ave, Miami, FL 33178 (FL WDD# #2220297) entered a settlement agreement for alleged violations of selling prescription drugs to an unauthorized recipient and failure to maintain proper records. Medline accepted a physician license for a customer which should have maintained a Healthcare Clinic Establishment Permit. The recordkeeping allegation related to missing NDC numbers on outbound packing slips and invoices. **Corrective Actions:** Medline updated customer licensing requirements for Florida customers and completed an extensive review of all FL customer licenses to verify the correct license type was on file. Medline determined the missing NDC number on the packing slip and invoice occurred due to an internal system error. The error was limited to DSCSA exempt products, i.e. IV fluids. A fix was implemented to correct the issue.

Medline Industries, LP- Discipline *Confidential*

07/19/2023 07/25/2023	1040 Enterprise Parkway South West Jefferson, OH 43162 251 Hilton Drive Jeffersonville, IN 47130	**Case:** A-2022-0307; A-2022-0184 **Agency:** Ohio Board of Pharmacy **Entity:** Medline Industries, LP **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, LP distribution centers at 1040 Enterprise Parkway South, West Jefferson, OH 43162 (OH License #01-30000190) and 251 Hilton Drive. Jeffersonville, IN 47130 (OH License #01-30000158) entered settlement agreements with the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. The sales occurred between July 2021 and January 2022. Medline maintained valid practitioner licenses on file for each customer instead of the correct d sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file instead of the correct Terminal Distributor Dangerous Drugs license (TDDD). Cases resolved via Settlement Agreement effective 07/19/2023 and 07/25/2023. **Corrective Actions:** Medline updated customer licensing requirements for Ohio customers following OH Case # A-2020-0054. The shipments in this matter occurred between July 2021 and January 2022 while Medline was in the process of reviewing and updating all Ohio customer licenses.
12/21/2023	2341 Lauwiliwili St. Kapolei, HI 96707	**Case:** PHA 2023-9-L **Agency:** Hawaii Department of Commerce and Consumer Affairs **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, LP distribution center at 2341 Lauwiliwili St, Kapolei, HI 96707 (HI #) entered a Settlement Agreement for discipline incurred in another jurisdiction (OH A-2022-0333, OH A-2022-0307, OH A-2022-0184, and FL 2022-031132) **Corrective Actions:** See corrective actions for OH A-2022-0333, OH A-2022-0307, OH A-2022-0184, and FL 2022-031132.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	08/03/2005	MO	Kansas City	Jackson

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2003031660	Missouri Board of Pharmacy

Reason/Charge
Failure to Renew on Time; Temperature Control Deficiency

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
MO Board of Pharmacy/ Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries Inc. distribution center at 1401 N. Universal Ave, Kansas City, MO 64120 (MO# DD2003031660) cited for failure to renew on time and deficient temperature control procedures. All issues resolved via Settlement Agreement effective 08/03/2005. License placed on probation for 5 years. The state conducted multiple inspections of the facility throughout the probationary period and found Medline to comply with all requirements. The probationary period closed in August 2010.

Corrective Actions:
Medline hired additional staff to monitor and ensure on-time license renewal. A temperature control room was constructed at the facility to ensure products are stored at the appropriate temperature and humidity.

Original Signature (electronic, copies or stamps not accepted)

07/30/26
Date

Jeremiah W. (Jay) Nixon
Governor
State of Missouri

Jane A. Rackers, Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance
Financial Institutions
and Professional Registration
John M. Huff, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573-751-0091 PHONE
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kimberly A. Grinston
Executive Director
www.pr.mo.gov/pharmacists.asp
e-mail: pharmacy@pr.mo.gov

08/03/2010

Charlie Mills
One Medline Place
Mundelein, IL 60060-4486

Dear Mr. Mills,

This is official notification that you have completed your terms of Probation with the Missouri Board of Pharmacy as of August 2, 2010.

If you have any questions, or if we can be of assistance in the future, feel free to contact this office. Thank you for complying.

Sincerely,

Jason Menken
Compliance Coordinator
Missouri Board of Pharmacy

Matt Blunt, Governor
State of Missouri

Alison Craighead, Director
Division of Professional Registration

Gregory A. Steinhoff, Director
Department of Economic Development

BOARD OF PHARMACY
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573-751-0091
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kevin E. Kinkade, R.Ph.
Executive Director

www.pr.mo.gov/pharmacists.asp
e-mail: pharmacy@pr.mo.gov

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
7160 3901 9848 6160 3154

August 4, 2005

Mr. Pete Furlong, Corporate Vice President
Quality Assurance/Regulatory Affairs
Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060-4486

Dear Mr. Furlong:

Enclosed is an executed copy of the **Settlement Agreement Between State Board of Pharmacy and Medline Industries, Inc.** A permanent drug distributor license, numbered 2003031660, has been issued to Medline Industries, Inc., 1401 N Universal Avenue, Kansas City, MO, and is being mailed to the facility with a copy of this letter. That license has been placed on probation August 3, 2005, through August 2, 2010.

A 2005-2007 Drug Distributor Renewal Application will be mailed to the facility within the next two weeks. This form must be completed and returned with the $400.00 fee before October 31, 2005.

You should review each term of this Agreement and comply with the requirements as set forth. Compliance is your responsibility; reminders will not be sent from this office. Licensee Report of Discipline Compliance forms are being included with the mailing to the facility and should be completed and submitted to the Board office within six months from the beginning of the probation period and every six months following that for the duration of the probation. Failure to comply with the terms of this Agreement may result in a violation hearing before the Board.

If you have any questions, please feel free to contact this office at 573-751-9056.

Sincerely,

DON WALKER
Drug Distributor Coordinator

Enclosures
cc: Rob Angstead, Attorney
Scott C Barbour, Manager-in-Charge

SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND MEDLINE INDUSTRIES, INC.

Come now Medline Industries, Inc. ("Respondent") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's license as a drug distributor will be subject to discipline.

Pursuant to the terms of § 536.060, RSMo (2000), the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under § 621.110, RSMo (2000), and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its license. Being aware of these rights provided it by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document, as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the Board, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's license. For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this

Settlement Agreement are true and stipulates with the Board that Respondent's temporary license as a drug distributor, License Number DD2003031660, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo 2000. The parties agree that this Settlement Agreement and any statements contained herein may not be used for or constitute an admission for any purposes other than to settle the disputes between the parties.

Joint Stipulation of Facts

1. Petitioner, the Missouri Board of Pharmacy ("the Board"), is an agency of the State of Missouri created and established by § 338.110, RSMo (2000), for the purpose of administering and enforcing the provisions of Chapter 338, RSMo.

2. Respondent, Medline Industries, Inc., located at 4700 Deramus, Kansas City, Missouri, is licensed by the Board as a drug distributor under the laws of Missouri, License Number DD2003031660. The license is current and active.

3. On or about April 16, 1996, Wilson Winch, an inspector for the Board, conducted an inspection at the facility located at 1691 N. Topping, Kansas City, Missouri.

4. Inspector Winch noted on the Drug Distributor Inspection Observation Report that Respondent needed temperature/humidity recording equipment and that the results must be logged daily.

5. On or about August 8, 1997, Tom Glenski, an inspector for the Board, conducted an inspection at the facility located at 1250 N. Southern, Kansas City, Missouri.

6. Inspector Glenski noted on the Drug Distributor Inspection Observation Report that Respondent needed a temperature and humidity daily log.

7. On or about September 3, 1997, the Board received a written response dated August 27, 1997, from Lara Simmons, Respondent's Director of Regulatory Affairs, explaining that a temperature and humidity monitoring device was being purchased and the temperature and humidity will be recorded daily during days of operation.

8. Ms. Simmons indicated that she anticipated the temperature and humidity monitoring device would be in place and the recordkeeping started by the first of September, 1997.

9. On or about July 31, 1998, Inspector Tom Glenski conducted an inspection at the facility located at 1250 N. Southern, Kansas City, Missouri.

10. Inspector Glenski noted on the Drug Distributor Inspection Observation Report that Respondent needed to keep daily temperature and humidity recordings.

11. Respondent failed to purchase the temperature and humidity monitoring device as Ms. Simmons indicated would be purchased.

12. Respondent's failure to provide an appropriate temperature and humidity monitoring device is in violation of 21 CFR § 211.46(b) which states:

> (b) Equipment for adequate control over air pressure, micro-organisms, dust, humidity, and temperature shall be provided when appropriate for the manufacture, processing, packing, or holding of a drug product.

13. On September 9, 1998, the Board sent a Compliance Letter to Respondent for a number of non-compliance issues found on the July 31, 1998 inspection, one of which was "temperature/humidity daily log documentation".

14. On or about September 2, 1999, Inspector Glenski conducted an inspection at the facility located at 1250 N. Southern, Kansas City, Missouri.

15. Inspector Glenski noted on the Drug Distributor Inspection Observation Report that the warehouse temperature exceeded the manufacturer's recommended storage temperature of 86 degrees Fahrenheit.

16. On or about October 4, 2000, Inspector Glenski conducted an inspection at the facility located at 1250 N. Southern, Kansas City, Missouri.

17. Inspector Glenski noted on the Drug Distributor Inspection Observation Report that the temperature exceeded 86 degrees on various days between July, 2000 and September, 2000.

18. On or about September 20, 2001, Frank Van Fleet, an inspector for the Board, conducted a change-of-location inspection at the facility located at 4700 Deramus, Kansas City, Missouri.

19. Inspector Van Fleet noted on the Observation Report that the temperature exceeds 86 degrees on not less than 32 occasions between June 8, 2001 and September 5, 2001.

20. On or about May 21, 2003, Inspector Van Fleet conducted an inspection at the facility located at 4700 Deramus, Kansas City, Missouri.

21. Inspector Van Fleet noted on the Observation Report that the temperature exceeded 86 degrees on not less than 41 occasions between June 3, 2002 and September 30, 2002.

22. On or about August 19, 2003, Inspector Van Fleet conducted a follow-up inspection at the facility located at 4700 Deramus, Kansas City, Missouri.

23. Inspector Van Fleet monitored storage temperatures with a digital thermometer at various locations where prescription product was stored.

24. Three additional occasions were identified between September 30, 2002 and August 19, 2003 where the temperature exceeded 86 degrees.

25. Inspector Van Fleet found that storage temperatures were much higher than the temperatures Respondent had recorded on its log.

26. Inspector Van Fleet's digital thermometer registered a range from 89.1 degrees in one area where Respondent stored bulk prescription hydrating/electrolyte solutions to as high as 94.5 degrees in Respondent's over the counter storage area, but Respondent's temperature log records a temperature of 89 degrees for this date.

27. Inspector Van Fleet presented at the 4700 Deramus facility on March 2, 2004 for tbe purpose of conducting a new facility inspection.

28. Inspector Van Fleet found 16 occasions between October 31, 2003 and February 27, 2004 where the temperature in the warehouse dropped below 59 degrees.

29. Respondent's warehouse is divided into three areas by breezeways.

30. Respondent has only one digital monitor for 120,000 square feet of warehouse.

31. The warehouse is not air-conditioned, and even though it is heated, logs show product was stored at less than 59 degrees.

32. Respondent has a history of noncompliance regarding the storage of prescription product.

33. Monitoring temperature and/or storing product at manufacturer's recommended/required humidity and storage temperature has been an issue on every inspection since 1996 involving three different locations and three different inspectors.

34. Respondent has been in at least three different warehouses in the last six years and

has failed each time to choose a warehouse that is temperature controlled.

35. Drugs must be stored in accordance with manufacturer or USP guidelines and must be free of contamination, deterioration and adulteration.

36. Drugs stored outside of manufacturer or USP guidelines can become contaminated, deteriorated and adulterated.

37. A drug shall be deemed adulterated pursuant to 21 USC 351(a)(2)(B) which states:

> A drug or device shall be deemed to be adulterated –
>
> > (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to the safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess . . .

38. Respondent's failure to maintain a facility where temperature is controlled and humidity is maintained is in violation of 4 CSR 220-5.030(3)(B) which states in pertinent parts:

> (3) Minimum standards of practice for drug distributors shall include the following:
>
> > (B) The temperature of the facility where drugs are stored must be maintained within temperature requirements as provided for by the manufacturer or the latest edition of the *United States Pharmacopeia* (USP). Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, logs, or all of these, shall be utilized to document proper storage of prescription drugs.

(C) Appropriate housekeeping, sanitation, lighting, ventilation and humidity of all areas where drugs are stored must be maintained.

39. On or about April 16, 1997, Inspector Winch attempted an inspection at the facility located at 1691 N. Topping, Kansas City, Missouri and observed that Respondent had changed locations without notifying the Board.

40. Respondent's failure to timely notify the Board of its change of location and continue its operation as a wholesale drug distributor is in violation of 4 CSR 220-5.020(6) which states:

(6) If an individual or business entity operating a drug distributor facility changes the location of the facility either within the existing facility (structure) or to a new facility (structure), the facility shall not open for business at the new location until the board, its duly authorized agent or the Food and Drug Administration has inspected the premises of the new location and approved it and the facility has been in compliance with all state and federal drug laws pertaining to drug distribution. Upon the approval and receipt of a change of location fee, the board shall issue a permit authorizing operation of a facility at the new location and the permit shall bear the same number as the previous license. However, the license remains valid if the facility address changes, but not the location, and an amended license will be issued without charge under these circumstances.

41. On or about August 8, 1997, Inspector Glenski conducted an inspection at the facility.

42. The inspector noted on the Drug Distributor Inspection Observation Report that Respondent needed a complete policy and procedure manual.

43. On or about September 2, 1999, Inspector Glenski conducted an inspection at the facility located at 1250 N. Southern, Kansas City, Missouri.

44. Inspector Glenski noted on the Drug Distributor Inspection Observation Report

that Respondent's policy and procedure manual could not be located.

45. Respondent's failure to establish and maintain a completed policy and procedure manual is in violation of 4 CSR 220-5.030(3)(M) which states in pertinent parts:

> (3) Minimum standards of practice for drug distributors shall include the following:
>
> > (M) Wholesale drug and pharmacy distributors shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts and for correcting all errors and inaccuracies in inventories.

46. On October 31, 2003, Respondent's drug distributor license expired.

47. Respondent failed to renew its license by the renewal deadline of November 30, 2003.

48. Respondent's license became null and void on November 30, 2003.

49. The Board received a new application from Respondent on or about December 16, 2003.

50. The Board issued Respondent temporary license number 2003031660 on December 29, 2003.

51. From the time Respondent's license became null and void on November 30, 2003, until the Board's issuance of Respondent's temporary license on December 29, 2003, Respondent failed to display a valid license.

52. Respondent's failure to display a valid license is in violation of 4 CSR 220-5.020(8)(B) which states:

> (B) A license must be posted in a conspicuous place in the

facility to which it is issued.

53. Respondent's invoice number 1016623706 shows the distribution of several Irrigation Solutions to Heart of America Surgery Center in Kansas City, Kansas on December 4, 2003.

54. Respondent's invoice number 1016626229 shows the distribution of an Irrigation Solution and Lactated Ringers IV Solution to Physician's Surgery Center in Rolla, Missouri on December 4, 2003.

55. Respondent's invoice number 1016648194 shows the distribution of Dextrose in Normal Saline IV Solution to Logan Manor Nursing Home in Logan, Kansas on December 6, 2003.

56. Respondent failed to renew its distributor license on or before November 30, 2003 and it became null and void at that time.

57. Respondent continued to distribute prescription only product while its license was expired.

58. Respondent's failure to renew its license by the renewal deadline of November 30, 2003 and to continue to distribute prescription only product while its license was expired is in violation of Section 338.333.1, RSMo (2000) states in pertinent part:

> 1. No person or distribution outlet shall act as a wholesale drug distributor or pharmacy distributor without first obtaining license to do so from the Missouri board of pharmacy and paying the required fee. . . . No license shall be issued or renewed for a wholesale drug distributor or pharmacy distributor to operate unless the same shall be operated in a manner prescribed by law and according to the rules and regulations promulgated by the board of pharmacy with respect thereto. Separate licenses shall be required for each distribution site owned or operated by a wholesale drug distributor or pharmacy distributor.

59. Respondent's opening for business its operation as a wholesale drug distributor in a new location prior to inspection and approval of the Board is in violation of 4 CSR 220-5.020(6) which states:

> (6) If an individual or business entity operating a drug distributor facility changes the location of the facility either within the existing facility (structure) or to a new facility (structure), the facility shall not open for business at the new location until the board, its duly authorized agent or the Food and Drug Administration has inspected the premises of the new location and approved it and the facility has been in compliance with all state and federal drug laws pertaining to drug distribution. Upon the approval and receipt of a change of location fee, the board shall issue a permit authorizing operation of a facility at the new location and the permit shall bear the same number as the previous license. However, the license remains valid if the facility address changes, but not the location, and an amended license will be issued without charge under these circumstances.

Joint Conclusions of Law

60. Cause exists for Petitioner to take disciplinary action against Respondent's license under § 338.353(1), RSMo (Supp. 2002) which provides:

> 1. The board of pharmacy is hereby authorized and empowered, when complaints, examinations or inspection of wholesale drug distributor or pharmacy distributor disclose to the board that a wholesale drug distributorship or pharmacy distributorship is not being operated or conducted according to such legal rules and regulations and the laws of Missouri or any other sate or the federal government with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621, RSMo, charging the holder of a license to operate a drug distributorship or pharmacy wholesale operation constituting grounds for discipline in accordance with section 338.055.

61. Cause exists to discipline Respondent' license as a drug distributor pursuant to the

provisions of § 338.055, RSMo (Supp. 2002) which provides in pertinent part:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his certificate of registration or authority, permit or license for any one or any combination of the following causes:
>
> * * *
>
> (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter.
>
> * * *
>
> (12) Failure to display a valid certificate or license if so required by this chapter or any rule promulgated hereunder.
>
> * * *
>
> (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government.

Joint Agreed Disciplinary Order

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of §621.045.3, RSMo (2000):

1. Respondent's drug distributor license shall be placed on PROBATION for five (5) years pursuant to the provisions of Chapters 338 and 620, RSMo. During the period of

probation, Respondent will be entitled to operate as a drug distributor pursuant to Chapter 338, RSMo provided Respondent adheres to the following terms of probation:

A. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months, beginning six (6) months after this Order/Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of this disciplinary order.

B. Respondent shall pay all required fees for licensing to the Board and shall renew its license prior to October 31 for each licensing year.

C. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

D. If, after disciplinary sanctions have been imposed, Respondent ceases to keep its Missouri license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

E. The parties to this Order/Agreement understand that the Board of Pharmacy will maintain this Order/Agreement as an open record of the Board as provided in Chapters 338, 610 and 620, RSMo.

2. Upon the expiration of said discipline, Respondent's license as a drug distributor in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary

hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent.

3. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

4. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

5. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

6. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and

attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to § 536.087, RSMo, or any claim arising under 42 U.S.C. § 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

_____ REQUESTS

_____ DOES NOT REQUEST

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S LICENSE TO OPERATE AS A DRUG DISTRIBUTOR.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's license and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's license. Effective the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's license, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the

Settlement agreement goes into effect 15 days after the document is signed by the Board's Executive Director.

RESPONDENT

MEDLINE INDUSTRIES, INC.

By: _____

Pete Furlong
Corporate Vice President
Quality Assurance/Regulatory Affairs

Date: July 1, 2005

PETITIONER

MISSOURI BOARD OF PHARMACY

By: _____

Kevin Kinkade
Executive Director

Date: 7-19-05

HUSCH & EPPENBERGER, LLC

By: _____

Harvey M. Tettlebaum
235 East High Street
P.O. Box 1251
Jefferson City, MO 65102-1251
Telephone: 573/635-9118
Fax: 573/634-7854

Attorneys for Medline Industries, Inc.

NEWMAN, COMLEY & RUTH P.C.

By: _____

Robert K. Angstead #37795
601 Monroe, Suite 301
P.O. Box 537
Jefferson City, MO 65102-0537
Telephone: 573/634-2266
Fax: 573/636-3306

Attorneys for Missouri Board of Pharmacy

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	12/07/2006	GA	Lithia Springs	Douglas

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
N/A	Florida Department of Health

Reason/Charge
Medline's Florida Certified Designated Representative unexpectedly resigned.

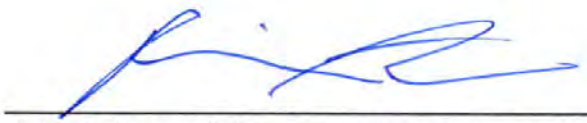
Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Florida Department of Health/ Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries Inc. distribution center at 9101 Riverside Pkwy Lithia Springs, GA 30122 Non-Resident FL Permit (FL # 23:1470) suspended for operating without a FL Certified Designated Representative. The CDR resigned unexpectedly. Upon receipt of the notice of intent to suspend, Medline stopped all shipments into the state of FL. Permit was reinstated upon hiring of a new licensed Florida CDR.

Corrective Actions:
Qualified FL Certified Designated Representative hired for facility. Medline implemented a policy requiring all FL licensed distribution centers to maintain a backup Florida Certified Designated Representative on staff.



Original Signature (electronic, copies or stamps not accepted)

07/30/26

Date

Medline Industries, Inc. One Medline Place Mundelein, Illinois 60060-4486 1.800.950.0128 Fax 1.847.949.2643

Corporate Quality Assurance/Regulatory Affairs

December 11, 2006

Ms. Rebecca R. Poston, R.Ph.
Executive Director
Drugs, Devices & Cosmetics Program
Florida Department of Health
4052 Bald Cypress Way
Tallahasee, FL 32399

RE: Prescription Drug Wholesaler Permit No. 23:01470

Dear Ms. Poston,

We have received the communication regarding the suspension of Prescription Drug Wholesaler Permit N. 23:01470. Pursuant to our communication with Rebecca Burnett on November 28, we have blocked applicable shipments from this location into Florida and they are being supplied by a properly permitted facility.

We are in the process of qualifying a replacement designated representative for this location. We hope to have this completed within the next 60 days.

Please note that Mr. Andy Stolarski is retiring and should no longer be listed as a contact for this location. Please direct any questions regarding this facility to
Ms. Lara Simmons
Corporate Director, Regulatory Affairs
One Medline Place
Mundelein, IL 60060
Phone: 847.837.2759
Fax: 847.837.2787
Email: LSimmons@Medline.com.

Sincerely,

Lara N. Simmons
Corporate Director, Regulatory Affairs

Dynacon Division
ISO9001
QUALITY SYSTEM REGISTERED
FM40001
MED/380/1/1065

Medisave Division
ISO9001
QUALITY SYSTEM REGISTERED
FM40001
MED/380/1/1065

OMI

CERTIFIED MAIL/RETURN RECEIPT REQUESTED

December 7, 2006

Andrew Stolarski
Vice President of Operations
Medline Industries, Inc.
9101 Riverside Parkway
Lithia Springs, GA 30122

RE: Prescription Drug Wholesaler Permit No. 23:01470

Dear Mr. Stolarski:

This letter serves as notification that the department intends to suspend permit no. 23:01470 issued to Medline Industries, Inc. as an Out of State Prescription Drug Wholesaler based upon the following facts, grounds and considerations:

Section 499.067(1)(a), Florida Statutes (F.S.), authorizes the department to deny, suspend, or revoke a permit if it finds that there has been substantial failure to comply with § 499.001-499.081, F.S., or Chapter 465, Chapter 501, or Chapter 893, the rules adopted under any of those sections or chapters, any final order of the department, or applicable federal laws or regulations or other state laws or rules governing drugs, devices, or cosmetics. The department may also suspend a permit if the applicant has not met the requirements for the permit.

Pursuant to s. 499.012(11)(a), F.S., each establishment that is issued an initial or renewal permit as a prescription drug wholesaler or an out-of-state prescription drug wholesaler must designate in writing to the department at least one natural person to serve as the designated representative of the wholesaler. Such person must have an active certification as a designated representative from the department and must also meet the requirements of Section 499.012 (11) (d) F.S.

Pursuant to s. 499.012(11)(f), F.S., a wholesale distributor may not operate under a prescription drug wholesaler permit or an out-of-state prescription drug wholesaler permit for more than 10 business days after the designated representative leaves the employ of the wholesale distributor, unless the wholesale distributor employs another designated representative and notifies the department within 10 business days of the identity of the new designated representative. Mr. David L. Magruder, the designated representative identified for permit no. 23:01470 has resigned his position. We have not received a "Notification of Designated Representative" form identifying a certified individual to replace him. As a result Medline Industries, Inc. does not have a designated representative as required by s. 499.012(11), F.S.

Pursuant to s. 499.012(11)(b)4., F.S., to be certified as a designated representative, a person must receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and ss. 499.001-499.081 and the rules adopted by the department governing the wholesale distribution of prescription drugs.

Accordingly, and pursuant to the above referenced facts and law, the department hereby intends to suspend permit no. 23:01470 issued to Medline Industries, Inc. as an Out of State Prescription Drug Wholesaler because you have not complied with s. 499.012(11)(f), F.S. and otherwise do not have a designated certified representative on file with the Department that meets the requirements of Section 499.012 (11) F.S. which is a substantial failure to comply with ss. 499.001 – 499.081, F.S. and is a failure to meet the requirements for the permit, for which the suspension is authorized pursuant to Sections 499.067 (1) (a); 499.067 (1) (b) 2. F.S.

Therefore, the department concludes that Medline Industries, Inc. no longer meets the requirements to continue to operate as an Out of State Prescription Drug Wholesaler in Florida and the permit will be suspended until you have designated in writing to the department a person with an active certification to serve as a designated representative who meets the requirements of Section 499.012 (11) F.S.

NOTICE OF RIGHTS TO HEARING AND APPEAL

You have the right to request an administrative hearing pursuant to sections 120.569 and 120.57, F.S., if you wish to challenge the intended agency action to suspend your permit. Such proceedings are governed by sections 120.569 and 120.57, F.S., and Rules 28-106 and 28-107, Florida Administrative Code. Request for a hearing, formal or informal, must comply with Rule 28-107.004, Florida Administrative Code.

You have the right to be represented by counsel or other qualified representative, at your expense; to present evidence and argument; to call and cross-examine witnesses; and to have subpoena and subpoena duces tecum issued on your behalf if a hearing is requested.

A petition for administrative hearing must be in writing and must be received by the Agency Clerk for the Department, within twenty-one (21) days from the receipt of this complaint. The address of the Agency Clerk is 4052 Bald Cypress Way, BIN # A02, Tallahassee FL 32399-1703. The Agency Clerk's facsimile number is 850-410-1448.

Mediation is not available as an alternative remedy.

Your failure to submit a petition for hearing within 21 days from receipt of this complaint will constitute a waiver of your right to an administrative hearing, under Florida Administrative Code Rule 28-106.111 and this complaint shall become a "final order".

Should this correspondence become a final order, a party who is adversely affected by it is entitled to judicial review pursuant to s 120.68, F.S. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings may be commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by the filing fees required by law, with the Court of Appeal in the appropriate District Court. The notice must be filed within 30 days of rendition of the final order.

Sincerely,

Rebecca R. Poston, R.Ph.
Executive Director
Drugs, Devices, & Cosmetics Program

RP/rb

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	02/08/2008	FL	Gainesville	Alachua

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2007-37412	Florida Department of Health

Reason/Charge
Inspection Deficiencies

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Florida Department of Health / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. distribution center at 2708 NE Waldo Rd., Gainesville, FL 32609 FL Permit (FL # 22:1022) suspended for violations identified during a Florida BOP facility inspection. Medline, through Counsel, addressed the issues raised in the inspection and established that the suspension was unjustified. The suspension was lifted 3 days later on January 22, 2008. Medline Industries, Inc. entered into a settlement agreement on 02/08/2008 with the FL Department of Health to resolve all issues related to the case.

Corrective Actions:
Medline conducted a thorough review of its policies and procedures and implemented an internal auditing program to ensure that all distribution centers comply with internal policies and procedures and state and federal regulations.



Original Signature (electronic, copies or stamps not accepted)

07/30/26

Date

Final Order No. DOH-08-0203-S-MQA
FILED DATE - 2-8-08
Department of Health
By: [signature]
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

Case No.: 2007-37412

vs.

MEDLINE INDUSTRIES, INC.,

Respondent.
_____/

FINAL ORDER

In this matter, the Florida Department of Health is proceeding under the Florida Drug and Cosmetics Act, Chapter 499, Florida Statutes. The Parties request a final order adopting their settlement agreement.

Being fully advised, the Parties' request is granted. On or about February 8, 2008, the Parties fully executed their "Settlement Agreement for Final Order", which is incorporated by reference. The "Settlement Agreement for Final Order" is approved, and the parties are directed to comply with it.

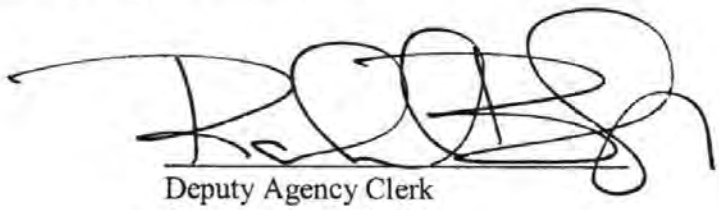
DONE and **ORDERED** this 8TH day of February 2008, in Tallahassee, Leon County, Florida.

ANA M. VIAMONTE ROS, M.D., M.P.H.
STATE SURGEON GENERAL

By: [signature]
PAUL METTS, C.P.A., M.H.A.
DEPUTY SECRETARY

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been furnished via U.S. Mail, or fax delivery to: Edwin Bayo, Esq., Attorney for MEDLINE INDUSTRIES, INC., at Metzger, Grossman, Furlow & Bayo, L.L.C , 1408 North Piedmont Way, Tallahassee, Florida 32308, 850.385.4240 (facsimile) and via interoffice mail to Lynne A. Quimby-Pennock, Assistant General Counsel, Department of Health, 4052 Bald Cypress Way, Bin #C-65, Tallahassee, Florida 32399-3265 this 8 day of February 2008.



Deputy Agency Clerk
Department of Health
4052 Bald Cypress Way, Bin C-01
Tallahassee, Fl. 32399-3251

DELEGATION OF AUTHORITY
to
Deputy Secretaries and Chief of Staff

A. In accordance with the authority created in Sections 20.05(1)(a) and (b) and 20.43, Florida Statutes and vested in me as State Surgeon General for the Department of Health, the following authority is delegated:

1. Take all actions required for the effective direction and administration of the Department of Health in accordance with applicable Florida Statutes (F.S.), Florida Administrative Code (F.A.C.), and department policies.

2. In the absence of the State Surgeon General, each deputy is delegated authority to sign as the agency head or represent the State Surgeon General at any meetings within their respective areas, unless there is a specific delegation of authority.

3. In the absence of a deputy, the other deputies are delegated the authority to take all actions required for the effective administration and operation of that respective area, unless there is a specific delegation of authority.

4. Act as a hearing officer in proceedings required by Section 120.54(3)(c), F.S., (Hearings) and to enter any order in connection therewith.

5. Enter final orders in proceedings under Section 120.57, F.S. (Additional Procedures Applicable to Hearings).

6. Authorize policies and procedures within your respective areas; however, all department-wide policy and procedure changes that affect or have an impact on other areas such as statewide computer systems, standard audit practices, and workload for the Division of Administration, shall be coordinated with the appropriate division director. **The State Surgeon General approves and signs all department policies.**

7. Approve contracts (revenue and expenditure) and purchase orders $1 million or more. This authority may not be redelegated. **Exception: Fixed Capital Outlay contracts, change orders and additional FCO services authorizations are delegated to the Director of Administration, who may only redelegate to the Chief of General Services or Administrator of Design and Construction.**

8. Approve all grant applications and carryover requests greater than $250,000. Bureau of Revenue Management approval required for Central Office grant applications prior to submission to the awarding agency.

9. Approve the hiring of Senior Management Service and Selected Exempt Service employees at a bureau chief level or higher pursuant to Chapter 60L-33, F.A.C., and department policy.

10. Grant Career Service employees salary additives in excess of 10% in accordance with Rule 60L-32.0011, F.A.C., and department policy.

11. Grant employees an increase to base rate of pay in excess of 10%in accordance with Rule 60L-32.0011, F.A.C., and department policy.

12. Approve appointments of employees previously dismissed from the department or other state agency. Approve appointments of employees who resigned from the department or other state agency while under investigation; or pursuant to a settlement agreement; or in lieu of dismissal.

13. Approve exemptions under Section 435.07, F.S., for persons disqualified from employment under Section 435.04, F.S.

14. Issue decisions on collective bargaining grievances at Step 2, in accordance with the Florida Statutes, department policy, and the applicable collective bargaining agreement.

15. Authorize and approve out-of-state travel.

16. Approve Emergency Suspension Orders and Emergency Restriction Orders during the absence of the State Surgeon General.

17. Approve core contracts under Chapter 154, F.S., with the local Board of County Commissioners.

B. Exceptions to this authority, which require the approval of the State Surgeon General are:

1. All changes to organization structure, functions, and programs involving the moving of positions or units between budget entities and divisions, or any action requiring the Department of Management Services and the Governor's Office of Policy and Budget approval.

2. Appointment or dismissal of county health department directors/administrators, children's medical services medical directors, division directors, or office directors.

C. This authority may be modified for specified periods of time as desired by the State Surgeon General.

D. These delegations may not be redelegated without the approval of the State Surgeon General.

8/6/07
Effective Date

Ana Maria Viamonte Ros
Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General
Department of Health

STATE OF FLORIDA
FLORIDA DEPARTMENT OF HEALTH
Medline Industries, Inc.
Case #2007-37412

SETTLEMENT AGREEMENT FOR FINAL ORDER

IT IS AGREED and STIPULATED by and between the State of Florida, Department of Health and MEDLINE INDUSTRIES, INC., that:

1. The Department of Health, through its Division of Medical Quality Assurance, Drugs, Devices and Cosmetics Program, (referred to as "the Department", 4052 Bald Cypress Way, Bin C-04, Tallahassee, Florida 32399 is responsible for, among other duties, under the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes (the Act) and the rules adopted there under, Rule 64F12 Florida Administrative Code, the regulation and permitting of prescription drug manufacturing and wholesaling within and into Florida.

2. The Department has investigated MEDLINE INDUSTRIES, INC., (referred to as "Medline") which holds a prescription drug wholesale permit, permit number 22:1022, located at 2708 NE Waldo Road, Gainesville, Floirda32609-3323.

3. The Department investigated Medline during the week of November 26, 2007, and found Medline to be operating in violation of Chapter 499, Florida Statutes (F.S.). The specific violations alleged include:

a. s. 499.005(1), & (4) F.S., and 499.069(1), F.S. in violation of s. 499.0121(1) F.S., and Rule 64F-12.014(4) Florida Administrative Code (F.A.C.) - holding or offering for sale any drug, device or cosmetic that is adulterated or

misbranded or has otherwise been rendered unfit for human or animal use. Establishment to be maintained in a clean and orderly manner to prevent the product from becoming contaminated with filth or injurious to health. (The surplus warehouse was unclean with spiders, spider webs, dead insect bodies, bird feces/droppings and feathers therein.)

b. ss. 499.005(1) & (4), F.S., in accordance to s. 499.006(9), F.S., holding for sale adulterated medical devices on its inventory shelves through a failure to quarantine outdated medical devices.

c. ss. 499.005(4), 499.0121, F.S. & Rules 64F-12.013, & 64F-12.015(7)(a) F.A.C., - Improper Prescription drug storage, lack of climate control.

d. s. 499.0121(3), F.S. – Failure to notify the Department of all prescription drug sources.

e. s. 499.005(14), F.S. – Receiving prescription drugs from an unauthorized source.

f. ss. 499.005(18), 499.0121(6), F.S., and Rules 64F-12.012(5), 64F12.001(2), and 64F-12.012(3)(a), F.A.C., – failure to have pedigrees readily available for inspection.

g. s. 499.0121(7), F.S., inadequate SOP (standard operating procedures) or P&P (policy and procedures), or failing to follow them.

h. s. 499.005(24), F.S., distribution of legend devices to the ultimate user without a prescription or order from practitioner.

i. s. 499.005(4), F.S., in violation of s. 499.0121(2), F.S.,- unrestricted access to prescription drugs in that prescription drugs, devices and/or cosmetics are left on a loading dock for pick-up/delivery, but the area does not have restricted access.

4. On or about November 27 and/or 28, 2007, seizure orders were placed on numerous items in Medline's surplus warehouse and one pallet of product within the climate-controlled warehouse.

5. On January 22, 2008, an Order of Emergency Restriction of Permit was issued by State Surgeon General, Ana M. Viamonte Ros, M.D., M.P.H., restricting the specific use of the facility.

6. A Final Order in this case will incorporate the following agreed upon terms and conditions:

a. All items under the seizure order that contain prescription drug products shall be destroyed at Medline's expense at a Florida Chapter 499, F.S., permitted facility; all other seized items shall be destroyed by Medline at Medline's expense. Within ten (10) days of the destruction, Medline shall submit documentation detailing the destruction of said items to the Compliance Officer of the Florida Drug, Device and Cosmetic Program, at 4042 Bald Cypress Way, MQA/HSE, Tallahassee, Florida 32399.

b. All products remaining at Medline's facility that were received from J & L Medical, Inc., located at 784 Old Checker Ct.,

Buffalo Grove, Illinois, between June 2007 through November 27, 2007, shall be destroyed at Medline's expense at a Florida Chapter 499, F.S., permitted facility, or if the products do not contain prescription drugs shall be destroyed by Medline at Medline's expense. Within ten (10) days of the destruction, Medline shall submit documentation detailing the destruction to the Compliance Officer of the Florida Drug, Device and Cosmetic Program, at 4042 Bald Cypress Way, MQA/HSE, Tallahassee, Florida 32399.

c. Medline shall pay a fine of FIFTY THOUSAND DOLLARS ($50,000.00) to the Florida Drug, Device and Cosmetic Trust Fund. Said payment shall be by certified check, cashier check or money, and shall accompany this executed Settlement Agreement. Said check shall be made payable to the Florida Drug, Device and Cosmetic Trust Fund.

d. The Order of Emergency Restriction, entered by the Department on January 22, 2008, shall be lifted upon the filing of the Final Order adopting and accepting the terms of this Settlement Agreement.

e. Medline shall undergo quarterly inspections by the Department at Medline's expense for one (1) year from the issuance of the Final Order, to ensure proper compliance with Chapter 499, Florida Statutes and the rules thereto. The Department shall provide an invoice for the inspection that shall be paid within thirty (30) days of receipt by Medline. Said payment shall be sent to the Compliance Officer of the

Florida Drug, Device and Cosmetic Program, at 4042 Bald Cypress Way, MQA/HSE, Tallahassee, Florida 32399. The Department retains the authority to enter the permitted facility/warehouse at any time to conduct inspections/investigations as authorized by Florida law.

f. Medline shall conduct a training program, within thirty (30) days of the execution of this Settlement Agreement For Final Order, for its facility employees educating the employees on the requirements of Chapter 499, Florida Statutes and the applicable rules. Within ten (10) days of the training, Medline shall submit documentation detailing the training to the Compliance Officer of the Florida Drug, Device and Cosmetic Program, at 4042 Bald Cypress Way, MQA/HSE, Tallahassee, Florida 32399.

g. Medline shall comply with all applicable Federal and state law and rules, including but not limited to Chapter 499 Florida Statutes, and its applicable rules. Medline shall comply with all pedigree and audit trail requirements for all prescription drugs purchased, held and /or distributed by Medline, including the authentication of any prescription drugs received. Medline shall ensure that any automated pedigree system employed, shall satisfy the requirements of Chapter 499, F.S. and the applicable rules thereto.

h. Medline shall maintain its facility in a clean, orderly and pest/bird free environment.

7. By execution of this Settlement Agreement For Final Order and by the filing of the subsequent Final Order in this cause, the Department and Medline intend to and do resolve all issues pertaining to the above referenced investigation.

8. Medline neither admits nor denies the violations allege in the inspection/investigation reports generated by the Department's investigators in this cause.

9. Upon entry of the Final Order adopting this Agreement, the Department will not seek further disciplinary action against Medline based on any of the alleged violations described in the above listed case number. However, if there are future violations of Chapter 499, F.S., or the rules adopted thereto, the above listed case will be considered aggravating circumstances and will be construed as previous violations for purposes of assessing the amount of the fine to be levied pursuant to section 499.066(3)(c), F.S.

10. Medline voluntarily enters into this Settlement Agreement for Final Order and waives the right to a hearing in this matter and all further proceedings to which it may be entitled by law or administrative rules. Medline hereby knowingly and voluntarily waives all right to challenge or to contest this Settlement Agreement or the Final Order issued by the Department in any forum now or in the future available to them, including the right to any administrative proceeding,

circuit or federal court action, or any appeal. Both parties agree not to appeal this Settlement Agreement or the Final Order to be issued in this matter.

11. The signatories hereto represent that they have read this Agreement and are authorized to execute it on behalf of their respective principals and as duly designated representatives, to fully bind such principals, as well as the Parties successors and assigns. The terms of this Agreement are effective on the date of the last signature below. The original will be filed with a Final Order with the Department Clerk. Each signer will receive a copy of this Agreement.

12. This document is a public record and contains information that is routinely published by the Department. Upon the filing of this Agreement and entry of a Final Order by the Department the existence of the above reference case number and all matters therein are no longer confidential and exempt from public disclosure. All documents or records created or submitted for compliance issues shall be a public record when filed with the Department.

13. Each party to this proceeding shall bear its own costs and attorney fees.

14. The absences of a prohibition specifically listed in this Agreement shall not be construed as permission to engage in any activity that otherwise is in violation of section 499.001-499.081, Florida Statutes, or the rules promulgated thereunder.

15. Upon the filing of this Settlement Agreement for Final Order, the parties, as well as any person who may claim by or through them, hereby waive,

release and discharge the other, and any of their employees, attorneys, agents or representatives from all claims arising out of any act or omission related to the investigation and settlement of this matter. This release applies to any and all claims of any kind, whether known or unknowns and whether direct, indirect or derivative.

16. Upon execution of this Agreement the State Surgeon General or her designee will issue a Final Order incorporating the terms hereof.

17. The parties agree that should any legal dispute arise concerning enforcing the terms of this Agreement, venue shall be in Leon County, Florida and this Agreement shall be interpreted in accordance with applicable Florida law.

WHEREFORE the Parties request a final order adopting this Agreement as final agency action.

For: Medline Industries, Inc.,

_____ February 7 2008
Lara N. Simmons
Corporate VP for QA and RA
Authorized Representative, Medline Industries, Inc.,

For the Department of Health - Drug, Device and Cosmetic Program
4052 Bald Cypress Way,
Tallahassee, Florida 32399, 850.245.4031 , 850.245.4682 Fax

_____ February 8 2008
Rebecca Poston, R.PH
Executive Director
Florida Drug, Device & Cosmetic Program
Department of Health

Medline Industries, Inc., Case #2007-37412

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	05/01/2008	LA	Covington	St. Tammany Parish

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2008006	Louisiana Board of Wholesale Drug Distributors

Reason/Charge
Customer Licenses

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
LA Board of WDD/ Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries Inc. distribution center at 149 New Camellia Blvd. Covington, LA 70433 (LA #4318) cited for failure to properly maintain copies of current customer licenses on-site. Licenses were maintained by Medline's Regulatory team at corporate headquarters. Medline entered a consent decree effective 05/01/2008 to resolve the alleged violation.

Corrective Actions:
Medline implemented digital storage of customer licenses to allow for on-demand access by distribution centers.

Original Signature (electronic, copies or stamps not accepted)

07/30/20
Date

LOUISIANA BOARD OF
WHOLESALE DRUG DISTRIBUTORS

MEDLINE INDUSTRIES, INC. Covington, LA LICENSE NO. 4318	CONSENT ORDER ADMINISTRATIVE CASE NO. 2008006

In review of evidence presented to the Louisiana Board of Wholesale Drug Distributors (the "Board") addressing specific violation(s) of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors by MEDLINE INDUSTRIES, INC., Covington LA facility (the "Respondent", "Licensee"), acting herein by its authorized agent, to-wit: "Copies of current licenses for customers who are authorized by law or regulation to procure or possess drugs or devices shall be maintained for all customers that are shipped or sold drugs or devices. If customer licenses are maintained off site, a list of customer names, addresses, licenses numbers, and license expiration dates shall be maintained for all customers that are shipped or sold drugs or devices.", La. R.S. Title 37, Chapter 54, Section 3467, and LAC Title 46, Part XCI, Section 311.D and "violating provisions of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors", La. R.S. Title 37, Chapter 54, Section 3474.1 and LAC Title 46, Part XCI, Section 101.

Upon consideration of the evidence presented to the Board, this Consent Order is voluntarily entered into by and between Respondent and the Board. Respondent acting through its authorized agent, hereby waives formal Notice of and its attendance at the Evidentiary Hearing for presentation of the Consent Order to the Board. However, as a condition precedent to submission of the proposed Consent Order to the Board, Respondent hereby acknowledges and understands that information may be presented to the Board with regards to the details of the case for the Board to understand the circumstances. It is further acknowledged and understood by Respondent that in the event the Board is not agreeable to enter into the proposed Consent Order and an Administrative Hearing is ultimately conducted, the Board which will be presiding over the case will possibly have heard information which may later be submitted at the scheduled hearing. If such hearing occurs, Respondent waives any right that it may have to recuse or remove any or all members of the Board for the purposes of an Administrative Hearing in the event the proposed Consent Order is not accepted by the Board, or if Respondent withdraws his consent to the proposed Consent Order prior to its final approval by the Board. Furthermore, Respondent has had the opportunity to, or has in fact consulted with, legal counsel with regards to the Consent Order and the waivers contained herein.

FINDINGS OF FACTS

1. Respondent possesses Louisiana License No. 4318 issued by the Board to wholesale distribute legend drugs and devices in the State of Louisiana. Such license was in effect on 3/5/2008 through the date of the evidentiary hearing in this matter.

2. Pursuant to LAC 46:XCI.311.D, a licensee is required to maintain copies of current licenses for customer who are authorized by law or regulation to procure or possess legend drugs or devices for all customers that are shipped or sold legend drugs or devices; if these license copies are maintained off site, a list of customers with customer names, addresses, license number, and license expiration dates shall be maintained on site for all customers shipped or sold legend drugs or devices.
3. On 3/5/2008, an inspection was conducted by the Board's representative which revealed that copies of customer licenses were not at the Covington LA facility. A verbal request to provide a customer listing which should be maintained at the Covington LA facility was made. The customer license list was not available.
4. Information was thereafter submitted by Respondent to the Board's inspector as per the inspector's request. In review of a customer listing ("Pedigree List") as provided by the Respondent, the inspector requested copies of customer licenses for 15 of the customers listed. Verbal explanation was given was that customer licenses are verified and the customer is entered electronically into the system as an authorized recipient but that no hard copy of the customer license is being maintained.
5. Respondent's conduct in failing to maintain customer license documents and/or a customer listing at the Covington LA site is in violation of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors, specifically LAC 46:XCI.311.D.
6. Disciplinary sanctions and/or fines are applicable against Respondent in accordance with the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors.

CONCLUSIONS OF LAW

1. It is unlawful for Respondent, as a licensee to wholesale distribute legend drugs and devices, to not maintain current customer license documents and/or a current customer listing on-site. LAC 46:XCI.311.D.
2. It is unlawful for Respondent, as a licensee to wholesale distribute legend drugs and devices, to violate any of the provisions of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors. La. R.S. 37:3474.1 and LAC 46:XCI.103
3. Respondent's violations of the provisions of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors constitute lawful grounds for the Louisiana Board of Wholesale Drug Distributors, upon due notice of hearing and proof of such violations, to assess a fine, revoke, suspend, or otherwise discipline Respondent's license as provided by law. La. R.S. 37:3474.1 and LAC 46:XCI.701 et seq.

DECISION

4. Respondent is hereby assessed a fine in the amount of $2,000 for its failure to properly maintain copies of current licenses for customers shipped or sold legend drugs or devices and/or a customer listing on site. Said fine to be paid on the effective date of

this Consent Order. No practice restrictions are placed on Respondent's license issued by the Board.

5. The existence and terms of this Consent Order will not be confidential or privileged information in accordance with the laws regarding public records.
6. Respondent hereby releases the Board, its representative, and attorney from any obligations or liability in their endeavors to administer this Consent Order.
7. The effective date of this Consent Order shall be such date it is accepted by the Board.
8. Respondent, through its authorized agent, declares that, before signing this Consent Order, it has carefully read this document, and it knows and understands the contents thereof, it signs it as an act of it own free will, it understands its meaning and effect, it has been given the opportunity to consult with an attorney, it voluntarily waives all rights to formal notice and a formal public hearing, as well as its appearance at the proceedings, and it consents to this Consent Order.

THUS DONE AND PASSED, on the 1 date of May, 2008 at the City of Mandeville, Parish/County of Lake, Louisiana/Illinois, in the presence of the two undersigned competent witnesses, who hereunto sign their names with Appearer and me, Notary, after due reading of the whole.

WITNESSES

Brenda Blanchard

Deborah Keefe

MEDLINE INDUSTRIES, INC.
Covington LA

Signature of Authorized Agent

Print Name of Authorized Agent

Notary Public

OFFICIAL SEAL
SUSAN MILLER
Notary Public - State of Illinois
My Commission Expires Jul 16, 2011

LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS
12046 Justice Avenue, Suite C
Baton Rouge, LA 70816
(225) 295-8567 Fax (225) 295-8568 lsbwdd@bellsouth.net www.lsbwdd.org

April 28, 2008

Lara N. Simmons, VP-QA/RA
MEDLINE INDUSTRIES, INC.
One Medline Place
Mundelein, IL 60060

RE: Louisiana License No. 4318
Administrative Docket No. 2008006

CERTIFIED MAIL
No. 7007 3020 0000 4431 9251
Return Receipt Requested

Dear Lara Simmons:

As you may recall, the Board is mandated by law to license and regulate the wholesale distribution of legend drugs and devices in Louisiana in accordance with the Louisiana Revised Statutes and Louisiana Administrative Codes for wholesale drug distributors. This letter will acknowledge receipt of your response dated 4/3/2008. This letter is also intended to respond to any inquiries you may have regarding the deficiencies found during the inspection which occurred on 3/5/2008 at MEDLINE INDUSTRIES, INC.'s Covington LA distribution facility.

Pursuant to the Louisiana Revised Statutes and Louisiana Administrative Codes, specifically LAC 46:XCI.311.D, a licensee should maintain copies of current licenses which authorizes a customer to procure and possess legend drugs and devices. If these customer licenses are maintained off site, a list of customers including customer names, addresses, license number, and the license expiration dates shall be maintained for all customers that are shipped or sold drugs or devices.

On 3/5/2008, the Board's inspector discovered that copies of customer licenses which authorize the customer to procure and possess legend drugs/devices or a listing of customers' license information were not being maintained at the Covington LA facility.

A verbal request was made by the inspector of a customer list which should have been maintained at the Covington LA facility. After receiving and reviewing a copy of the customer list, as referred to by Medline as their "Pedigree List", the inspector requested copies of 30 customer licenses from the listing. Of the requested customer license copies, the inspector found that 70% of the licenses requested were either not acceptable licenses or were not available.

It is evident that MEDLINE INDUSTRIES, INC. was in violation of LAC 46:XCI.311.D at the time of the inspection on 3/5/2008. The Louisiana Revised Statutes and Louisiana Administrative Codes for wholesale drug distributors, more particularly LA RS 37:3474.1, provides that, after due notice and hearing, MEDLINE INDUSTRIES, INC.'s license may be sanctioned and/or it may be assessed a fine for its actions or omissions. Fines alone may include an assessment of $1,000 per violation

Ben Bronfin, Chairman
Al Isaac Cates, Vice-Chairman
Randall Brooks, Secretary-Treasurer
John Diggle, Executive Director/Inspector
Dardar Daw, Board Member
Wayne Hamilton, Board Member
Jay Miller, Board Member
Kenneth D. Barron, Executive Assistant

per day. It is the Board's objective to regulate the industry by correcting behavior. Such is accomplished by imposing sanctions for wrongful conduct.

It is hoped that the above detailed violation(s) as corrected will not occur in the future. Therefore, in an effort to amicably resolve the issues regarding the violation(s) which did occur, I, as the Board's appointed investigating/compliance officer, extend an offer to you which would impose a total fine of $2,000. This proposed sanction does not impose any restrictions on MEDLINE INDUSTRIES, INC.'s license.

If MEDLINE INDUSTRIES, INC. is agreeable to these terms, I have enclosed a Consent Order for your review and execution. Please have an authorized representative for your company sign the Consent Order in front of a Notary and two witnesses. Return the original, executed Consent Order along with a check made to the Louisiana Board of Wholesale Drug Distributors in the amount of the $2,000 fine to the Board's office within fifteen (15) days of receipt of this letter. You and/or a company representative will not be required to attend the evidentiary hearing at which the executed Consent Order will be presented to the full Board for acceptance, however you and/or another representative are welcome to attend.

In the event MEDLINE INDUSTRIES, INC. is not agreeable to this amicable resolution and wishes to contest the investigative findings in a hearing before the full Board, it has the right to do so. If such occurs, the current offer being proposed in this letter will no longer be viable.

We would like to bring this matter to disposition either by this amicable resolution or the pursuit of a formal hearing against MEDLINE INDUSTRIES, INC. before the Board at the next scheduled Board meeting. To do so, either way, we will need to prepare the necessary paperwork with all resolution documents. Again, please respond to this offer either by returning the executed Consent Order and fine payment or by written request for an administrative hearing. If your response is not received at the Board office within fifteen (15) days of receipt of this letter, the Board will begin steps towards the formal hearing with the issuance of subpoenas for witnesses and records.

We wish to keep an open line of communication with you. Please contact the Board office in the event you have any questions. Thank you for your cooperation in this matter.

Respectfully,

Wayne Bremullion
Board Member/Compliance Officer

kbb
Encl: Consent Order
File
c.c. Harry H. Schaecher, Covington LA

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	07/08/2008	HI	Waipahu	Honolulu

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
PHA 2008-71-L	Hawaii Department of Commerce and Consumer Affairs

Reason/Charge
Late Discipline Reporting

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
HI DCCA / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. distribution center at 94-1420 Moaniani St., Waipahu, HI 96797 (HI # PWD 115) entered a settlement agreement and placed on probation for 5 years for failure to report disciplinary actions within 30 days. Medline submitted all required notices but missed the 30-day deadline. The probationary period ended in August 2013.

Corrective Actions:
Medline implemented a policy and procedure to notify licensing boards of disciplinary actions within the required reporting timelines.

Original Signature (electronic, copies or stamps not accepted)

07/30/26
Date

LINDA LINGLE
GOVERNOR

JAMES R. AIONA, JR.
LT. GOVERNOR

LAWRENCE M. REIFURTH
DIRECTOR
DEPARTMENT OF COMMERCE AND
CONSUMER AFFAIRS

JO ANN M. UCHIDA
COMPLAINTS AND
ENFORCEMENT OFFICER

STATE OF HAWAII
REGULATED INDUSTRIES COMPLAINTS OFFICE
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
LEIOPAPA A KAMEHAMEHA BUILDING
235 SOUTH BERETANIA STREET, NINTH FLOOR
HONOLULU, HAWAII 96813
FAX: (808) 586-2670
TELEPHONE: (808) 586-2660

HILO OFFICE
345 KEKUANAOA STREET, SUITE 12
HILO, HAWAII 96720

KONA OFFICE
KEAUHOU SHOPPING CENTER, ROOM
134A
78-6831 ALII DRIVE
KAILUA-KONA, HAWAII 96740

MAUI OFFICE
1063 LOWER MAIN STREET, SUITE C-216
WAILUKU, HAWAII 96793

KAUAI OFFICE
3060 EIWA STREET, ROOM 204
LIHUE, HAWAII 96766

July 8, 2008

Ms. Dianna J. Wolfe
Regulatory Affairs Specialist
Medline Industries, Inc.
One Medline Place
Mundelein, Illinois 60060

Re: RICO Case No. PHA 2008-71-L

Dear Ms. Wolfe:

I received the signed Settlement Agreement. One correction had to be made, and I apologize that we did not notice this earlier. On page 3, paragraph 5, the citation to HRS section 436B-19(13) was changed to HRS section 436B-19(15) which is the correct citation. Enclosed is a copy of the corrected replacement page. I will now forward the document to the executive officer of the Board of Pharmacy, and we will be notified as to whether it gets approved or not by the Board.

Very truly yours,

Bobbi Lum-Mew

Bobbi W.Y. Lum-Mew
Staff Attorney

/BLM
Enclosure

Attachment 6b.

DARIA A. LOY-GOTO 6175
BOBBI W.Y. LUM-MEW 6299
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorney for Department of Commerce
and Consumer Affairs

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Wholesale Prescription Drug Distributor's License of	)	PHA 2008-17-L
MEDLINE INDUSTRIES INC.,	)	SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHBITS "1" THROUGH "5"
Respondent.	)	

241092407

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorneys, and Respondent MEDLINE INDUSTRIES INC. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS

1. At all relevant times herein, Respondent was licensed by the Board of Pharmacy (hereinafter the "Board") as a wholesale prescription drug distributor under License Number

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

PWD 115. The license was issued on or about October 3, 2005. The license will expire on or about December 31, 2009.

2. Respondent's mailing address for purposes of this action is One Medline Place, Mundelein, Illinois 60060.

3. RICO received information that disciplinary action had been taken against Respondent's licenses by the States of Missouri and Florida. Specifically, RICO received information regarding the following:

a). Respondent entered into a Settlement Agreement with the Missouri State Board of Pharmacy. Pursuant to the terms of a Joint Agreed Disciplinary Order, Respondent's Missouri drug distributor's license was placed on probation and Respondent was ordered to comply with certain terms and conditions. A true and correct copy of the Settlement Agreement and Joint Agreed Disciplinary Order dated July 19, 2005 in Settlement Agreement Between State Board of Pharmacy and Medline Industries, Inc., is attached as Exhibit "1";

b). Respondent was issued a Letter of Warning and Notice of Serious Violations by the Missouri State Board of Pharmacy. A true and correct copy of the Letter of Warning and Notice of Serious Violations dated February 15, 2007 regarding Medline Industries, Inc., is attached as Exhibit "2";

c). Respondent was issued an Order of Emergency Suspension of Permit by the State of Florida's Department of Health. Pursuant to the terms of the Order, Respondent's Florida prescription drug wholesaler's permit was immediately suspended . A true and correct copy of the Order of Emergency Suspension of Permit by the State of Florida's Department of Health dated January 14, 2008 in In Re: Emergency Suspension of the Permit of Medline Industries, Inc., is attached as Exhibit "3";

d). Respondent was issued an Order of Emergency Restriction of Permit by the State of Florida's Department of Health. Pursuant to the terms of the Order, Respondent's Florida prescription drug wholesaler's permit was immediately restricted. A true and correct copy of the Order of Emergency Restriction of Permit by the State of Florida's Department of Health dated January 22, 2008 in In Re: Emergency Restriction of the Permit of Medline Industries, Inc., is attachec as Exhibit "4";

e). Respondent entered into a Settlement Agreement with the State of Florida's Department of Health. Pursuant to the terms of a Final Order, Respondent was, among other things, ordered to undergo quarterly inspections and pay a $50,000.00 fine. A true and correct copy of the Settlement Agreement for Final Order dated February 8, 2008 in Settlement Agreement for Final Order regarding Medline Industries, Inc., is attached as Exhibit "5."

4. RICO alleges that although Respondent reported the actions on a December 5, 2007 renewal application, Respondent failed to report the disciplinary actions within thirty (30) days as required by Hawaii law.

5. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(15) (failure to report disciplinary action within thirty days) and § 436B-19(17) (violating applicable laws or rules).

6. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein licensed as a wholesale prescription drug distributor by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the license and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's license.

6. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

7. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2008-17-L.

C. TERMS OF SETTLEMENT:

1. Probation. Respondent's wholesale prescription drug distributor's license is hereby placed on probation for a period of five (5) years. During the probationary period, Respondent agrees to comply with the following terms of the probation as set forth in paragraphs C.2, C.3, and C.4 below:

2. Comply with Terms of Missouri Probation. Respondent shall comply with the terms of its probation in the July 19, 2005 Settlement Agreement Between State Board of Pharmacy and Medline Industries, Inc.. During the probationary period, Respondent shall report to the Hawaii Board of Pharmacy, in writing, any additional action by the State of Missouri within ten (10) days of such action. During the probationary period, Respondent shall deliver to the Hawaii Board proof of Respondent's compliance with the Missouri Settlement Agreement.

3. Comply with Terms of Florida Final Order. Respondent shall comply with the terms of the February 8, 2008 Settlement Agreement for Final Order. During the probationary period, Respondent shall report to the Hawaii Board of Pharmacy, in writing, any additional action by the State of Florida within ten (10) days of such action. During the probationary period, Respondent shall deliver to the Hawaii Board proof of Respondent's compliance with the Florida Settlement Agreement.

4. Administrative fine. Respondent agrees to pay a fine in the amount of FIVE THOUSAND AND NO/100 DOLLARS ($5,000.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: Bobbi Lum-Mew, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this fully executed Settlement Agreement is returned to RICO.

5. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1, C.2, C.3 and C.4 above, Respondent's license shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the license to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new license until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become licensed again, Respondent must apply to the Board for a new license pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

6. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of wholesale prescription drug distributors in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

7. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.8, C.9, C.10 and C.11 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

8. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

9. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

10. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any

representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

11. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: _____, _____, _____.

MEDLINE INDUSTRIES INC.

By: _____
Its _____

DATED: Honolulu, Hawaii, JUL 0 8 2008.

DARIA A. LOY-GOTO
BOBBI W.Y. LUM-MEW
Attorneys for Department of Commerce and Consumer Affairs

IN THE MATTER OF THE WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR'S LICENSE OF MEDLINE INDUSTRIES INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; PHA 2008-17-L; EXHIBITS "1" THROUGH "5"

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

ELWIN D.H. GOO
Chairperson

DATE

MARK E. BROWN
Vice-Chairperson

LAURIE H. Y. KAWAMURA

KENT KIKUCHI

KARL H. MIYAMOTO

PATRICK ADAMS

STANLEY M. CHOW

PVL 09/05/07

STATE OF Illinois)
) SS.
COUNTY OF Lake)

On this 5 day of July, 200 8, before me personally appeared Lisa Simms, to me known to be the person described, and who executed the foregoing instrument on behalf of Medline Industries as Corporate VP of C+I/CT, and acknowledged that he/she executed the same as his/her free act and deed.

OFFICIAL SEAL
SUSAN MILLER
Notary Public - State of Illinois
My Commission Expires Jul 16, 2011

Name:
Notary Public, State of

My Commission expires: 7-16-2011

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	9/06/2008	FL	Multiple	Multiple

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
See Below	Florida Department of Health

Reason/Charge
Pedigree, Incorrect Permit, Distribution to Unauthorized Receipt, Storage

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
FL DOH / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.; Medline Manufacturing & Services, LLC

Provide explanation below:

Medline Industries Inc. and Medline Manufacturing & Services, LLC was cited for several violations related to distribution centers in Florida, including, failure to pass and maintain a Florida compliant pedigree, maintaining the wrong permit type for the activities performed (Florida required a repackager permit in addition to the existing manufacturer permit), distribution of saline to an unauthorized recipient, and storage of a prescription drug in an unlicensed raw materials storage facility. Medline challenged several violations, resulting in most being substantially reduced or removed. All issues were addressed and resolved to the satisfaction of the FL DOH. A settlement agreement was reached to resolve all matters and approved on 09/06/2008.

Corrective Actions
Medline instituted a Florida specific pedigree system to address the pedigree issues. The updated pedigree ensures that all applicable shipments to Florida have the required Florida documentation and comply with FL pedigree requirements (Note - these requirements have since been preempted by the federal Drug Supply Chain Security Act). Medline secured the repackaging permit to address the missing permit type. Medline instituted a new procedure for obtaining and maintaining customer licenses for all prescription drug purchases- this procedure generates an automatic block for any prescription drug order by an unlicensed customer. The prescription drug item unintentionally stored in the raw materials facility was properly disposed of and waste disposal procedures updated to prevent this from occurring in the future.

Locations:
10601 Southport Dr., Orlando, FL 32824
401 Commerce Blvd, Oldsmar, FL 34677
4750 118th Ave N, Clearwater, FL 33762

Case #: 2007-11783; 2007-36555; 2007-38894; 2007-38895; 2007-38896; 2007-39073; 2008-02011; 2008-11215



Original Signature (electronic, copies or stamps not accepted)

07/30/20
Date

Attachment 5.

Final Order No. DOH-08-2129-S-MQA
FILED DATE - 9-19-08
Department of Health
By: [signature]
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

Case No.: 2007-11783; 2007-36555;
2007-38894; 2007-38895;
2007-38896; 2007-39073;
2008-02011; 2008-11215

vs.

MEDLINE, INDUSTRIES, INC.,

Respondent.

FINAL ORDER

A Notice of Violation letter was sent to the Respondent by the Department on May 14, 2008. Having received an Offer of Settlement, which is attached hereto as Exhibit A, this matter is before the Department of Health for the entry of a final order.

The Offer of Settlement was executed on or about September 19, 2008 and submitted together with the payment.

The Offer of Settlement is accepted and incorporated by reference. The parties are directed to comply with the terms of the Agreement.

It is, therefore, ORDERED that this matter and proceeding be CLOSED.

DONE and **ORDERED** this 26 day of September 2008, in Tallahassee, Leon County, Florida.

ANA M. VIAMONTE ROS, M.D., M.P.H.
State Surgeon General

By: Rebecca R. Poston

Rebecca R. Poston, R.Ph.
Executive Director
Drugs, Devices and Cosmetics

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been furnished via U.S. mail to: **Edwin Bayo, Esq., Attorney for MEDLINE INDUSTRIES, INC., at Metzger, Grossman, Furlow & Bayo, L.L.C., 1408 North Piedmont Way, Tallahassee, Florida 32308**, this 29 day of September, 2008.

Deputy Clerk

cc: Lynne Quimby-Pennock, DOH 4052 Bald Cypress Way, Bin #C-65 Tallahassee, FL 32399
Richard Sands, DOH 4052 Bald Cypress Way, Bin #C-70

SETTLEMENT AGREEMENT

Medline Industries, Inc., Case No.: 2007-11783, Permit No.: 22:596; Case No.: 2007-36555, Permit No.: No valid permit since 12.21.2006; Case No. 2007-38894, Permit No. 20:168; Case No. 2007-38895, Permit No.: 21:166; Case No. 2007-38896, Permit No.: 07:545; Case No.: 2007-39073, Permit No.: None; Case No. 2008-02011, Permit No.: None; Case No. 2008-11215, Medline Manufacturing & Services, LLC Permit No.: None

Pursuant to Section 120.57(4), Florida Statutes (2007), the above named parties hereby enter into this global stipulation as disposition of the attached administrative action, in lieu of any other administrative proceedings authorized in Chapter 120, Florida Statutes. The terms herein become effective upon rendition of the final order which shall incorporate the Settlement Agreement.

STIPULATED FACTS

1) Medline Industries Inc., and Medline Manufacturing & Services, LLC, (hereinafter collectively known as "Medline") neither admit nor deny the alleged violations in the attached Notice of Violation.
2) During the time the alleged violations occurred, Medline held certain Florida permits including: Permit No.: 22:596, a prescription drug wholesaler; Permit No.:20:168, a prescription drug manufacturer; Permit No.: 21:166 an Over the Counter Manufacturer; and Permit No.: 07:545 a device manufacturer within the state of Florida; however Medline is alleged to have failed to have certain other permits in the Notice of Violation.
3) The Department is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 20.43, Florida Statutes (2007), and Chapter 499, Florida Statutes (2007).

EXHIBIT
A
0460

CONCLUSIONS OF LAW

4) Medline, by and through its undersigned agent, admits that it is subject to the provisions of Chapter 499, Florida Statutes (2007), and the jurisdiction of the Department.

5) Medline admits that the findings set forth in the Notice of Violation, if proven, would constitute violations of Chapter 499, Florida Statutes (2007).

6) Medline agrees that the Department's acceptance of the Settlement Agreement constitutes disciplinary action within the meaning of Section 499.066, Florida Statutes (2007), and Rule 64F-12.024, Florida Administrative Code.

SETTLEMENT

7) Medline agrees to pay a fine of ONE HUNDRED FIFTY THOUSAND DOLLARS ($150,000.00), and acknowledges that payment, made payable to the Florida Drug, Device and Cosmetic Trust Fund, is enclosed with this agreement.

8.) Medline affirms the violations cited the Notice of Violation letter issued under these case numbers have been corrected or are being corrected immediately. Medline shall provide written documentation of the return of the seized products to a licensed reverse distributor within thirty (30) days of the execution of this agreement. The documentation shall be sent to the Florida Drug Device and Cosmetic Program Office, Department of Health, 4052 Bald Cypress Way, Bin C04, Tallahassee, FL 32399-3255. Upon receipt of documentation demonstrating the return of the seized products, the seizure order shall automatically be lifted.

9) Medline affirms that it shall comply with all provisions of the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes, and the rules adopted thereunder.

10) It is expressly understood that a violation of the terms of this Settlement Agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary actions may be taken.

11) Medline expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Settlement Agreement incorporated in the Final Order.

12) Medline waives the right to seek any attorney's fees or costs from the Department in connection with this disciplinary proceeding.

Corporate Seal:

By: _____ 9/19/08
President (or authorized agent) Date

Attested by: _____ _____
Corporate Secretary Date

By: Rebecca R Poston 9/26/08
Authorized DOH Representative Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	02/04/2009	WI	Wausau	Marathon

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
08 PHM 037	Wisconsin Department of Regulation and Licensing

Reason/Charge
Failure to Separate Products, Failure to retrieve Policies and Procedure during Inspection

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
WI DSPS/ Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries Inc. distribution center at 5450 W. Stewart Ave., Wausau, WI 54401 (WI # 1116-045) cited for missing policies and procedures and storage of drugs in a non-secure location following an inspection by the Wisconsin Department of Regulation & Licensing. Medline managed a portion of a Wisconsin hospital's warehouse. The inspector cited Medline for failure to install a dividing fence between the Medline warehouse and the hospital portion of the facility. All hospital products were owned by the hospital. Medline was also cited for failure to access policies and procedures during the inspection. Corrections were made and the facility re-inspected, to the satisfaction of the state. Medline entered a stipulation order effective 02/04/2009 to resolve the matter.

Corrective Actions:
Medline installed a locked fence to separate the hospital's owned products. Medline also completed a review of all facilities to ensure proper separation of products. On-site staff provided additional training on how to access current policies and procedures during an inspection.



Original Signature (electronic, copies or stamps not accepted)

07/30/20

Date

Jim Doyle
Governor

Celia M. Jackson
Secretary

WISCONSIN DEPARTMENT OF REGULATION & LICENSING

1400 E Washington Ave
PO Box 8935
Madison WI 53708-8935
Email: web@dri.state.wi.us
Voice: 608-266-2112
FAX: 608-266-2264
TTY: 608-267-2416

November 18, 2008

Jan Hornick
Medline Industries Inc.
5450 W. Stewart Ave.
Wausau, WI 54401

Re: 08 PHM 037

Dear Ms. Hornick:

As you know, an inspector for the Department of Regulation and Licensing inspected Medline Industries on May 9, 2008. He found that several policies were missing, and the facility was storing prescription drugs in a non-secure location. It has been determined that these violations are grounds for discipline. I am the prosecuting attorney assigned to the case.

I have enclosed a proposed stipulation and order, which would resolve this matter without a hearing. If you are willing to resolve this case by agreement, please sign and return the stipulation and order **by December 9, 2008**. I will then present it to the Pharmacy Examining Board at its next meeting. The stipulation and order is not binding unless and until it is accepted by the board.

If you do not return the signed stipulation and order by December 9, 2008, I will file a formal complaint and initiate the hearing process. Please be aware that it is the policy of the Department to assess costs against respondents whenever any discipline is imposed. Your costs are presently $100. If we have to take this matter through a hearing, they will escalate quickly and could reach several thousand dollars.

Please call if you have any questions.

Sincerely,

Jeanette Lytle
Attorney
Division of Enforcement
608-266-9840

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
MEDLINE INDUSTRIES INC. RESPONDENT.	:	STIPULATION LS# _____

Division of Enforcement Case # 08 PHM 037

Respondent Medline Industries Inc., by its manager Jan Hornick; and Jeanette Lytle, attorney for the Department of Regulation and Licensing, Division of Enforcement, stipulate:

1. This Stipulation is entered into as a result of a pending investigation of Respondent's licensure by the Division of Enforcement (case # 08 PHM 037). Jan Hornick represents, by her signature below, that she has authority to enter into this agreement on behalf of Respondent. Ms. Hornick, on behalf of Respondent, consents to the resolution of this investigation by stipulation.

2. Respondent's manager, Jan Hornick, understands that by signing this Stipulation she voluntarily and knowingly waives on behalf of Respondent its rights, including: the right to a hearing on the allegations against it, at which time the state has the burden of proving those allegations by a preponderance of the evidence; the right to confront and cross-examine witnesses; the right to call witnesses and to compel their attendance by subpoena; the right to testify; the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision; the right to petition for rehearing; and all other applicable rights afforded to it under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and any other provisions of state or federal law.

3. Respondent has been provided an opportunity to obtain the advice of legal counsel prior to signing this stipulation.

4. Jan Hornick agrees, on behalf of Respondent, to the adoption of the attached Final Decision and Order by the Pharmacy Examining Board. The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall be returned to the Division of Enforcement for further proceedings. In the event that this Stipulation is

not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by consideration of this attempted resolution.

6. The parties to this Stipulation agree that the attorney or other agent for the Division of Enforcement and any member of the Pharmacy Examining Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of the Respondent or its attorney, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with the Board's deliberations on the Stipulation. Additionally, any such Board advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's final decision and order is a public record and will be published in accordance with standard Department procedure.

8. The Division of Enforcement joins Jan Hornick in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.

Medline Industries Inc.

By: Jan Hornick _____ 11-24-08

Jan Hornick, manager
5450 West Stewart Avenue
Wausau, WI 54401

Date

_____ _____

Jeanette Lytle
Attorney
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935
Madison, WI 53708-8935

Date

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
MEDLINE INDUSTRIES INC., RESPONDENT.	:	LS # _____

Division of Enforcement Case # 08 PHM 037

The parties to this action for the purposes of Wis. Stat. § 227.53 are:

Medline Industries Inc.
5450 W. Stewart Ave.
Wausau, WI 54401

Division of Enforcement
Department of Regulation and Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

Pharmacy Examining Board
Department of Regulation & Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

PROCEDURAL HISTORY

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Pharmacy Examining Board. The Board has reviewed the attached Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. Medline Industries Inc. is duly licensed as a wholesale distributor of prescription drugs in Wisconsin (license # 45-1116). This license was first granted on June 21, 1999.

2. Respondent's most recent address on file with the Wisconsin Pharmacy Examining Board is 5450 W. Stewart Avenue, Wausau, Wisconsin 54401.

3. The Department of Regulation and Licensing conducted an unannounced inspection on May 9, 2008. The following violations were noted:

(a) The following policies were missing: Recall policy [Wis. Admin. Code § Phar 13.15(2)], Emergency plan [Wis. Admin. Code § Phar 13.15(3)], Outdated stock policy [Wis. Admin. Code § Phar 13.15(4).

(b) Respondent was storing Complete Delivery Systems (pre-packaged kits for surgeries, including various types and quantities of prescription drugs) in a warehouse it shared with another company. The CDS kits were not secured and employees of the other company had unhindered access to the kits, in violation of Wis. Admin. Code § Phar 13.10(3).

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter, pursuant to Wis. Stat. §450.10, and is authorized to enter into the attached Stipulation and Order, pursuant to Wis. Stat. § 227.44(5).

2. The conduct described in paragraph 3 above constitutes a violation of Wisconsin Administrative Code § Phar 13.10(3), Phar 13.15(2), (3) and (4), and Wis. Stat. § 450.10(1)(a)2 and 6 and subjects Respondent to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

ORDER

IT IS ORDERED:

1. Medline Industries Inc. is REPRIMANDED.

2. Respondent shall, within ninety (90) days from the date of this Order, pay a FORFEITURE in the amount of Two Thousand Dollars ($2,000.00).

3. Respondent shall, within ninety (90) days from the date of this Order, pay costs of this proceeding in the amount of One Hundred Dollars ($ 100.00). Payment shall be made payable to the Wisconsin Department of Regulation and Licensing, and mailed to:

Department Monitor
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935

Madison, WI 53708-8935
Telephone (608) 267-3817
Fax (608) 266-2264

4. In the event Respondent fails to pay the forfeiture as ordered, or in the event it fails to pay costs as ordered, Respondent's license (#45-1116) SHALL BE SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of this Order.

5. This Order is effective on the date of its signing.

Dated this __ day of _____, 2008.

PHARMACY EXAMINING BOARD

By: _____
A Member of the Board

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
MEDLINE INDUSTRIES INC., RESPONDENT.	:	LS # 0902046PHM

Division of Enforcement Case # 08 PHM 037

The parties to this action for the purposes of Wis. Stat. § 227.53 are:

Medline Industries Inc.
5450 W. Stewart Ave.
Wausau, WI 54401

Division of Enforcement
Department of Regulation and Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

Pharmacy Examining Board
Department of Regulation & Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

PROCEDURAL HISTORY

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Pharmacy Examining Board. The Board has reviewed the attached Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. Medline Industries Inc. is duly licensed as a wholesale distributor of prescription drugs in Wisconsin (license # 45-1116). This license was first granted on June 21, 1999.

2. Respondent's most recent address on file with the Wisconsin Pharmacy Examining Board is 5450 W. Stewart Avenue, Wausau, Wisconsin 54401.

3. The Department of Regulation and Licensing conducted an unannounced inspection on May 9, 2008. The following violations were noted:

(a) The following policies were missing: Recall policy [Wis. Admin. Code § Phar 13.15(2)], Emergency plan [Wis. Admin. Code § Phar 13.15(3)], Outdated stock policy [Wis. Admin. Code § Phar 13.15(4).

(b) Respondent was storing Complete Delivery Systems (pre-packaged kits for surgeries, including various types and quantities of prescription drugs) in a warehouse it shared with another company. The CDS kits were not secured and employees of the other company had unhindered access to the kits, in violation of Wis. Admin. Code § Phar 13.10(3).

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter, pursuant to Wis. Stat. §450.10, and is authorized to enter into the attached Stipulation and Order, pursuant to Wis. Stat. § 227.44(5).

2. The conduct described in paragraph 3 above constitutes a violation of Wisconsin Administrative Code § Phar 13.10(3), Phar 13.15(2), (3) and (4), and Wis. Stat. § 450.10(1)(a)2 and 6 and subjects Respondent to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

ORDER

IT IS ORDERED:

1. Medline Industries Inc. is REPRIMANDED.

2. Respondent shall, within ninety (90) days from the date of this Order, pay a FORFEITURE in the amount of Two Thousand Dollars ($2,000.00).

3. Respondent shall, within ninety (90) days from the date of this Order, pay costs of this proceeding in the amount of One Hundred Dollars ($ 100.00). Payment shall be made payable to the Wisconsin Department of Regulation and Licensing, and mailed to:

Department Monitor
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935

Madison, WI 53708-8935
Telephone (608) 267-3817
Fax (608) 266-2264

4. In the event Respondent fails to pay the forfeiture as ordered, or in the event it fails to pay costs as ordered, Respondent's license (#45-1116) SHALL BE SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of this Order.

5. This Order is effective on the date of its signing.

Dated this 1 day of February, 2009.

PHARMACY EXAMINING BOARD

By: _____
A Member of the Board

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	05/19/2009	HI	Waipahu	Honolulu

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
PHA 2009-7-L	Hawaii Department of Commerce and Consumer Affairs

Reason/Charge
Discipline incurred in another jurisdiction

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
HI DCCA / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. agreed to enter a Consent Order for discipline incurred in another jurisdiction (Wisconsin Case #: 08 PHM 037).

Original Signature (electronic, copies or stamps not accepted)

07/30/26
Date

BOBBI W.Y. LUM-MEW 6299
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorney for Department of Commerce
and Consumer Affairs

2009 MAY 22 A 9:24 2009 MAY 19 A 9:4

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Wholesale Prescription Drug Distributor's License of	)	PHA 2009-7-L
MEDLINE INDUSTRIES INC.,	)	SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"
Respondent.	)	

241092407

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorneys, and Respondent MEDLINE INDUSTRIES INC. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS

1. At all relevant times herein, Respondent was licensed by the Board of Pharmacy (hereinafter the "Board") as a wholesale prescription drug distributor under License Number PWD 115. The license was issued on or about October 3, 2005. The license will expire on or about December 31, 2009.

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

2. Respondent's mailing address for purposes of this action is Dianna Wolfe, Corporate Regulatory Affairs Specialist, Medline Industries, Inc., One Medline Place, Mundelein, Illinois 60060.

3. Respondent timely reported that disciplinary action had been taken against Respondent by the State of Wisconsin. Respondent had entered into a Stipulation with the State of Wisconsin's Pharmacy Examining Board. Pursuant to the terms of a Final Order, Respondent was reprimanded and ordered to pay a forfeiture in the amount of $2,000.00. This action was based on the results of an inspection which revealed that certain policies were missing and that Respondent was storing pre-packaged kits for surgeries (which included various types and quantities of prescription drugs) in a warehouse that was shared with another company. These kits were not secured and employees of the other company had access to the kits. A true and correct copy of the Stipulation and Final Decision and Order which was approved on February 4, 2009 is attached as Exhibit "1."

4. RICO alleges that Respondent was disciplined by another state for a reason provided by the licensing laws in Hawaii. Specifically, the Respondent was disciplined for professional misconduct.

5. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(13) (disciplinary action by another state) and § 461-21(a)(2) (professional misconduct). Per Hawaii Administrative Rules §§ 16-95-30(c)(6) and (9), a licensee's facility must be secure from unauthorized entry and entry into areas where prescription drugs are held must be limited to authorized personnel.

6. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein licensed as a wholesale prescription drug distributor by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the license and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's license.

6. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

7. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2009-7-L.

C. TERMS OF SETTLEMENT:

1. Administrative fine. Respondent agrees to pay a fine in the amount of ONE THOUSAND AND NO/100 DOLLARS ($1,000.00). Payment shall be made by **cashier's check, company check, or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: Bobbi Lum-Mew, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due within thirty (30) days after this Settlement Agreement is approved by the Board.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph C.1 above, Respondent's license shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the license to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new license until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become licensed again, Respondent must apply to the Board for a new license pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of wholesale prescription drug distributors in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5, C.6, C.7 and C.8 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: Mundelein (CITY), IL (STATE), 5/11/09 (DATE).

MEDLINE INDUSTRIES INC.

By: [signature]
Its Pres. of GAIRA

DATED: Honolulu, Hawaii, MAY 19 2009.

[signature]
DARIA A. LOY-GOTO
BOBBI W.Y. LUM-MEW
Attorneys for Department of Commerce and Consumer Affairs

IN THE MATTER OF THE WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR'S LICENSE OF MEDLINE INDUSTRIES INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER: PHA 2009-7-L; EXHIBIT "1"

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

ELWIN D.H. GOO
Chairperson

June 18, 2009
DATE

MARK E. BROWN
Vice-Chairperson

LAURIE H. Y. KAWAMURA

KENT KIKUCHI

KARL H. MIYAMOTO

PATRICK ADAMS

STANLEY M. CHOW

PVL 05/20/08

STATE OF Illinois)
) SS.
COUNTY OF Lake)

On this 11 day of May, 2009, before me personally appeared Lee V Simms, to me known to be the person described, and who executed the foregoing instrument on behalf of Mallie Industries as President, GA/RA, and acknowledged that he/she executed the same as his/her free act and deed.

OFFICIAL SEAL
SUSAN MILLER
Notary Public - State of Illinois
My Commission Expires Jul 16, 2011

Name: Susan Miller
Notary Public, State of IL

My Commission expires: July 16, 2011

2009

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
MEDLINE INDUSTRIES INC., RESPONDENT.	:	LS # 0902046PHM

Division of Enforcement Case # 08 PHM 037

The parties to this action for the purposes of Wis. Stat. § 227.53 are:

Medline Industries Inc.
5450 W. Stewart Ave.
Wausau, WI 54401

Division of Enforcement
Department of Regulation and Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

Pharmacy Examining Board
Department of Regulation & Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

PROCEDURAL HISTORY

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Pharmacy Examining Board. The Board has reviewed the attached Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. Medline Industries Inc. is duly licensed as a wholesale distributor of prescription drugs in Wisconsin (license # 45-1116). This license was first granted on June 21, 1999.

EXHIBIT "1"

2. Respondent's most recent address on file with the Wisconsin Pharmacy Examining Board is 5450 W. Stewart Avenue, Wausau, Wisconsin 54401.

3. The Department of Regulation and Licensing conducted an unannounced inspection on May 9, 2008. The following violations were noted:

(a) The following policies were missing: Recall policy [Wis. Admin. Code § Phar 13.15(2)], Emergency plan [Wis. Admin. Code § Phar 13.15(3)], Outdated stock policy [Wis. Admin. Code § Phar 13.15(4).

(b) Respondent was storing Complete Delivery Systems (pre-packaged kits for surgeries, including various types and quantities of prescription drugs) in a warehouse it shared with another company. The CDS kits were not secured and employees of the other company had unhindered access to the kits, in violation of Wis. Admin. Code § Phar 13.10(3).

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter, pursuant to Wis. Stat. §450.10, and is authorized to enter into the attached Stipulation and Order, pursuant to Wis. Stat. § 227.44(5).

2. The conduct described in paragraph 3 above constitutes a violation of Wisconsin Administrative Code § Phar 13.10(3), Phar 13.15(2), (3) and (4), and Wis. Stat. § 450.10(1)(a)2 and 6 and subjects Respondent to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

ORDER

IT IS ORDERED:

1. Medline Industries Inc. is REPRIMANDED.

2. Respondent shall, within ninety (90) days from the date of this Order, pay a FORFEITURE in the amount of Two Thousand Dollars ($2,000.00).

3. Respondent shall, within ninety (90) days from the date of this Order, pay costs of this proceeding in the amount of One Hundred Dollars ($ 100.00). Payment shall be made payable to the Wisconsin Department of Regulation and Licensing, and mailed to:

Department Monitor
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935

Madison, WI 53708-8935
Telephone (608) 267-3817
Fax (608) 266-2264

4. In the event Respondent fails to pay the forfeiture as ordered, or in the event it fails to pay costs as ordered, Respondent's license (#45-1116) SHALL BE SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of this Order.

5. This Order is effective on the date of its signing.

Dated this 4 day of February, 2009.

PHARMACY EXAMINING BOARD

By: _____
A Member of the Board

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF :
DISCIPLINARY PROCEEDINGS AGAINST :
:
MEDLINE INDUSTRIES INC. :
RESPONDENT. :

STIPULATION
LS#0902046PHM

Division of Enforcement Case # 08 PHM 037

Respondent Medline Industries Inc., by its manager Jan Hornick; and Jeanette Lytle, attorney for the Department of Regulation and Licensing, Division of Enforcement, stipulate:

1. This Stipulation is entered into as a result of a pending investigation of Respondent's licensure by the Division of Enforcement (case # 08 PHM 037). Jan Hornick represents, by her signature below, that she has authority to enter into this agreement on behalf of Respondent. Ms. Hornick, on behalf of Respondent, consents to the resolution of this investigation by stipulation.

2. Respondent's manager, Jan Hornick, understands that by signing this Stipulation she voluntarily and knowingly waives on behalf of Respondent its rights, including: the right to a hearing on the allegations against it, at which time the state has the burden of proving those allegations by a preponderance of the evidence; the right to confront and cross-examine witnesses; the right to call witnesses and to compel their attendance by subpoena; the right to testify; the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision; the right to petition for rehearing; and all other applicable rights afforded to it under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and any other provisions of state or federal law.

3. Respondent has been provided an opportunity to obtain the advice of legal counsel prior to signing this stipulation.

4. Jan Hornick agrees, on behalf of Respondent, to the adoption of the attached Final Decision and Order by the Pharmacy Examining Board. The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall be returned to the Division of Enforcement for further proceedings. In the event that this Stipulation is

not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by consideration of this attempted resolution.

6. The parties to this Stipulation agree that the attorney or other agent for the Division of Enforcement and any member of the Pharmacy Examining Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of the Respondent or its attorney, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with the Board's deliberations on the Stipulation. Additionally, any such Board advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's final decision and order is a public record and will be published in accordance with standard Department procedure.

8. The Division of Enforcement joins Jan Hornick in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.

Medline Industries Inc.

By: Jan Hornick 11-24-08

Jan Hornick, manager
5450 West Stewart Avenue
Wausau, WI 54401

Date

12/10/08

Jeanette Lytle
Attorney
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935
Madison, WI 53708-8935

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	03/19/2010	MO	Kansas City	Jackson

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2010-002994	Colorado State Board of Pharmacy

Reason/Charge
Conditional License

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
CO Board of Pharmacy / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. distribution center at 1401 N. Universal Ave, Kansas City, MO 64120 applied for a Colorado Out-of-State Wholesaler license. The CO Board of Pharmacy issued a conditional license until the facility's MO probation period ended. (See Case 2003031660 above). Medline informed the CO Board when the MO probationary period was completed. Upon completion of probation, the Board issued a full license.

Corrective Actions:
Medline successfully completed terms of probation in MO and CO.

Original Signature (electronic, copies or stamps not accepted)

07/30/26
Date

Dora
Department of Regulatory Agencies

Division of Registrations
Rosemary McCool
Director

State Board of Pharmacy
Wendy Anderson
Program Director

Bill Ritter, Jr.
Governor

Barbara J. Kelley
Executive
Director

March 24, 2010

MedLine Industries, Inc.
Attn: Scott C. Barbour, Designated Representative
1401 N. Universal Ave.
Kansas City MO 64120

RE: Stipulation and Final Agency Order
Case #2010-2994

IN THE MATTER OF DISCIPLINARY RPOCEEDINS REGARDING THE LICENSE TO PRACTICE AS A OUT-OF-STATE WHOLESALER IN THE STATE OF COLORADO CF MEDLINE INDUSTRIES, INC.,

Dear Mr. Barbour:

Enclosed you will find a copy of the fully executed Stipulation and Final Agency Order (Stip/FAO) n the above mentioned matter, which became effective March 19, 2010.

Accordingly, and pursuant to Conditional Registration, item 9, of the Stip/FAO, MedLine Industries. Inc., at the above listed location, has been issuec out-of-state prescription drug wholesaler registration #7713, with conditions, effective March 23, 2010.

Medline Industries, Inc., Colorado out-of-state wholesaler registration #7713 shall be probationary pending the Colorado State Board of Pharmacy's receipt of a request for discharge from Medline Industries, Inc., which must include documentation showing Medline Industries, Inc.'s release from the terms and conditions of the Missouri Settlement Agreement effective 8/3/05.

If you have any questions, or require additional information, please feel free to contact me at (303) 894-2989.

Respectfully,

FOR THE COLORADO STATE BOARD OF PHARMACY

Tia Johnson
Complaint Analyst
Enclosure
cc: Beth Thompson, Vice President, Regulatory Affairs, Medline Industries, Inc.
John Steele, Settlement Specialist, Office of Expedited Settlement
Jazell Carter, Licensing Specialist, Office of Licensing
File

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2010-002994

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE LICENSE TO PRACTICE AS A OUT-OF-STATE WHOLESALER IN THE STATE OF COLORADO OF MEDLINE INDUSTRIES, INC.,

Wholesaler Applicant.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Medline Industries, Inc. ("Wholesaler Applicant") to resolve all matters pertaining to Board Case Number 2010-002994 as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Wholesaler Applicant, its application for registraticn as an out-of-state wholesaler and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S.

2. Wholesaler Applicant admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

3. Wholesaler Applicant entered into a Settlement Agreement with the Missouri State Board of Pharmacy, which was effective on August 3, 2005 ("Missouri Settlement Agreement").

4. In the Missouri Settlement Agreement, Wholesaler Applicant was placed on probation for five (5) years for various violations of Missouri state and federal law involving recordkeeping, storage of prescription drugs, change of location without informing the Missouri Board of Pharmacy, lack of a policy and procedure manual, and distribution of prescription drugs under a lapsed registration.

5. Wholesaler Applicant's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes:

12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(III) Any state or federal law pertaining to drugs.

12-22-125.2. Disciplinary actions.

(1) The board may deny or discipline an applicant, licensee, or registrant when the board determines that such applicant, licensee, or registrant has engaged in activities that are grounds for discipline.

6. On January 14, 2010, Wholesaler Applicant submitted an out-of-state wholesaler application, which application was denied by the Board.

7. On March 1, 2010, Wholesaler Applicant submitted a written request asking that the Board accept its application by granting a conditional license.

8. The Board finds and concludes, and Wholesaler Applicant agrees, that based upon Wholesaler Applicant's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances as a condition of its registration as an out-of-state wholesaler.

DISPOSITION

Conditional Registration / Probation / Compliance / Terms

9. **Conditional Registration**. Wholesaler Applicant shall be granted a registration as an out-of-state wholesaler upon execution of this Final Agency Order and satisfaction of the terms and conditions set forth herein.

10. **Probation**. Wholesaler Applicant's registration shall be placed on probation for a period of time equal to the time of probation remaining under the Missouri Settlement Agreement. Credit toward satisfying the period of probation under this Final Agency Order shall be given only during such periods of time that Respondent is in total compliance with all provisions of this Final Agency Order and the Missouri Settlement Agreement.

11. **Compliance.** Wholesaler Applicant shall at all times remain in compliance with §§12-22-801, *et seq.* C.R.S. and shall not at any time distribute prescription drugs into Colorado without being registered as an out-of-state wholesaler in the State of Colorado at the time of distribution.

12. **Other Requirements.** Wholesaler Applicant acknowledges and agrees that, as a condition of this Final Agency Order and probation, Wholesaler Applicant shall:

    a. promptly pay all Wholesaler Applicant's own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

13. **Discharge.** Discharge from the requirements of this Final Agency Order must be requested in writing by Wholesaler Applicant. The Board will consider any request for discharge during the ordinary course of business. In any request for discharge it shall be Wholesaler Applicant's sole responsibility to establish, through written and other documentation, that Wholesaler Applicant has met all terms and conditions of this Final Agency Order and, in addition, has been released from probation by the Missouri Board of Pharmacy under the Missouri Settlement Agreement. Wholesaler Applicant's probation under this Final Agency Order shall continue until formally discharged by the Board by way of Board order.

14. **Advisements and Waivers.** Wholesaler Applicant enters into this Final Agency Order freely and voluntarily, whether or not Wholesaler Applicant has consulted with legal counsel. Wholesaler Applicant acknowledges its understanding that it has the following rights:

    a. To have a formal notice of hearing and charges served upon it;
    b. To respond to said formal notice of charges;
    c. To have a formal disciplinary hearing pursuant to §12-22-125, C.R.S.; and
    d. To appeal this Board order.

    Wholesaler Applicant freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

15. **Acknowledgments.** The undersigned authorized agent of Wholesaler Applicant has read this Final Agency Order in its entirety and acknowledges, whether or not Wholesaler Applicant has consulted with legal counsel, that Wholesaler Applicant

understands the legal consequences and agrees that none of the terms or conditions herein are unconscionable.

16. **Violations.** Time is of the essence to this Final Agency Order. It is the responsibility of Wholesaler Applicant to take all appropriate steps to comply fully with this Final Agency Order. Wholesaler Applicant acknowledges and agrees that any violation of this Final Agency Order may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Wholesaler Applicant to comply with all terms and conditions of this Final Agency Order.

17. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

18. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

19. **Effective Date.** This Final Agency Order shall become effective upon signature of a Board member or representative.

ACCEPTED AND AGREED BY

Dana N. Simmons Dated: 3/12/10

Authorized Agent of Wholesaler Applicant

Subscribed and sworn to by Dana N. Simmons, in his/her capacity as an authorized agent of Medline Industries, Inc., before me in the County of Lake, State of Illinois, this 12 day of March, 2010.

OFFICIAL SEAL
SUSAN MILLER
Notary Public - State of Illinois
My Commission Expires Jul 16, 2011

Susan Miller

Notary Public

My commission expires: 7-16-2011

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 19th day of March, 2010.

State Board of Pharmacy

BY: Wendy Anderson

Wendy Anderson
Program Director

CERTIFICATE OF MAILING

This is to certify that I have duly mailed the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 5th day of March 2010, addressed as follows:

Medline Industries, Inc.
Attn: Scott C. Barbour, Designated Representative
1401 N. Universal Ave.
Kansas City, MO 64120

Beth Thompson
Vice President, Regulatory Affairs
Medline Industries, Inc.
1 Medline Pl.
Mundelein, IL 60060

John C. Steele

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 24th day of March 2010, addressed as follows:

Medline Industries, Inc.
Attn: Scott C. Barbour, Designated Representative
1401 N. Universal Ave.
Kansas City, MO 64120

Beth Thompson
Vice President, Regulatory Affairs
Medline Industries, Inc.
1 Medline Pl.
Mundelein, IL 60060

Agent of the Board

Dora
Department of Regulatory Agencies

Division of Registrations
Rosemary McCool
Director

State Board of Pharmacy
Wendy Anderson
Program Director

Bill Ritter, Jr.
Governor

Barbara J. Kelley
Executive
Director

August 25, 2010

MedLine Industries, Inc.
Attn: Scott C. Barbour, Designated Representative
1401 N. Universal Ave.
Kansas City, MO 64120

RE: Stipulation and Final Agency Order (Stip/FAO), effective 3/19/10
Case #2010-2994

Dear Mr. Barbour:

Staff for the Colorado State Board of Pharmacy ("Board") has reviewed the material concerning Medline Industries' request for release from the terms and conditions of the above listed Stip/FAO effective 3/19/10.

After due consideration, and pursuant to Board Policy 10-6, staff for the Board released Medline Industries, Inc., from the terms and conditions of the 3/19/10 Stip/FAO, and restored its out-of-state prescription drug wholesaler registration #7713 to unencumbered status, effective 8/25/10.

Your cooperation during the pendency of this matter is sincerely appreciated.

Sincerely,

FOR THE COLORADO STATE BOARD OF PHARMACY

Wendy L. Anderson
Program Director

cc: Beth Thompson, Vice President, Regulatory Affairs, Medline Industries, Inc.
File

1560 Broadway, Suite 1350 Denver, Colorado 80202 Phone 303.894.7800
Fax 303.894.7692 www.dora.state.co.us V/TDD 711
Consumer Protection

Policy Number: 10-6

Title: Delegation of Authority to Program Director or Section Director

Date Issued: 11/16/2006

Dates Revised: 8/21/08, 10/16/08, 9/17/09, 1/21/10, 7/15/2010

PURPOSE: To clarify the authority which has been delegated to the Program Director, Section Director, or his/her designee

POLICY: The Board of Pharmacy has delegated to the Program Director, Section Director or his/her designee the authority to

1. Sign Stipulations and Final Agency Orders ("Stipulations") and final orders issued subsequent to initial decisions entered after hearings held by administrative law judges ("Final Board Orders") on its behalf
2. Issue Final Board Orders on its behalf when no exceptions are filed to the initial decision, the statutorily allowed time frame for the filing of exceptions has passed, the recommended sanction from the Administrative Law Judge is the same as that sought by the Board, and no further decisions are required by the Board
3. Process reports of settlement of malpractice claims in the same manner as signed complaints are handled
4. Accept, on the Board's behalf, practice and treatment monitoring reports and any other such reports submitted as required by the Stipulation or Final Board Order, provided such reports are in compliance with the terms of the Stipulation or Final Board Order
5. Initiate complaints and issue 30-day letters to licensees or registrants currently under Stipulation or Final Board Order if, in the opinion of the Program Director or his/her designee, the licensee or registrant has failed to comply with any of the terms of his or her stipulation
6. Sign Suspension Orders as required by the Child Support Enforcement Program
7. Subpoena documents and gather information in order to assist the Board in carrying out its duties
8. Approve practice monitors for licensees and registrants as required pursuant to Stipulations or Final Board Orders
9. Sign suspension orders on its behalf
10. Sign cease and desist orders on its behalf
11. Perform the initial review of complaints relating to the practice of licensees or registrants under the Board's jurisdiction and to issue 30-day letters relating to the complaints
12. Initiate complaints and issue 30-day letters where otherwise authorized by the Board
13. Determine non-substantive procedural matters relating to the rendering of initial decisions, including, but not limited to, granting extensions of time for the filing of exceptions, and granting requests for oral argument
14. Perform additional delegated duties as set forth in Board policies

15. Make referrals for assessment to the Pharmacy Peer Assistance Diversion Program.

16. Suspend the licenses of individuals under Stipulation or Final Board Order if licensee is required to participate in the Pharmacy Peer Assistance Diversion Program as a requirement of his/her Stipulation or Final Board Order and fails to comply with his/her contract with the Rehabilitation Evaluation Committee. The Program Director or his/her designee may lift the Board suspension on such licenses when the licensee has resumed compliance.

17. Release licensees and registrants from the terms of their Stipulations or Final Board Orders provided the licensee submits satisfactory evidence of completion of all terms of the Stipulation or Final Board Order. The Program Director or his/her designee, at his/her discretion, may refer any request for discharge to the Board for review.

18. Deny requests from licensees and registrants for discharge from the terms of Stipulations or Final Board Orders when the licensee or registrant has not completed the terms of the Stipulation or Final Board Order. Requests for early discharge from Stipulations and Final Board Orders shall be denied.

19. Suspend the licenses or registrations of facilities which have been ordered to pay a fine pursuant to a Stipulation or Final Board Order and fail to remit the required payment. In the event the licensee or registrant is to pay the fine in installments, the Program Director or his/her designee may suspend the license or registration if the licensee or registrant fails to remit a required payment. The Program Director or his/her designee may lift the Board suspension on such licenses or registrations when the licensee or registrant has come into compliance with fine requirements.

20. Enter, on its behalf, written agreements with public or private entities whereby the Board may provide information from the Electronic Prescription Drug Monitoring Program that does not identify a patient, prescriber, or dispenser of a prescription drug. Such agreements may only be entered into for the purposes of bona fide research or education pursuant to CRS 12-22-705(5).

21. Notice, on its behalf, proposed rules or proposed amendments or deletions to rules for a hearing before the board pursuant to CRS 24-4-103.

22. In the absence of additional exculpatory evidence or information not previously before the board, reject any counteroffer from respondents with cases at the Office of Expedited Settlement that is not within the board's settlement parameters.

23. Issue on its behalf, the "Board Procedural Order regarding Review of Initial Decision" upon receipt of an Initial Decision from an Administrative Law Judge at the Office of Administrative Courts.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	7/18/2014	NY	Middletown	Orange

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
27278	NY State Education Department- Board of Pharmacy

Reason/Charge
Discipline incurred in another jurisdiction

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
NY Board of Pharmacy / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. agreed to enter a Consent Order for discipline incurred in another jurisdiction (FL No. 2007-37412, LA No. 2008006, and WI No. 08 PHM 037).

Corrective Actions:
See corrective actions for FL No. 2007-37412, LA No. 2008006, and WI No. 08 PHM 037.

Original Signature (electronic, copies or stamps not accepted)

07/30/24
Date

THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK

OFFICE OF PROFESSIONAL DISCIPLINE
(212) 921-3872/3873

1411 BROADWAY – TENTH FLOOR
NEW YORK, NEW YORK 10018

July 18, 2014

Medline Industries Inc., Pharmacy Wholesaler
3301 Route 6
Middletown, NY 10940

Re: License No. 028250

Dear Sir or Madam:

Enclosed please find Order No. 27278. This letter will explain when the Order regarding the above respondent goes into effect.

If the penalty imposed by the Order is an annulment, revocation, surrender, or an actual suspension (suspension which is not wholly stayed) of your license, you must deliver your license and registration to this Department within ten (10) days after the date of this letter.

In the event you are personally served with the Order, the Order is effective as of the date of the personal service. In the event you are served by certified mail and are not personally served with the Order, the Order is effective five (5) days after the date of this letter. The Order will take effect as indicated in this letter, even if you fail to meet the time requirement of delivering your license and registration to this Department.

If the penalty imposed by the Order is a revocation or a surrender of your license, you may, pursuant to Rule 24.7 (b) of the Rules of the Board of Regents, a copy of which is attached, apply for restoration of your license after three years have elapsed from the effective date of the Order and the penalty. Please be advised that said application is not granted automatically.

The record and reports of a disciplinary proceeding or resulting voluntary settlement shall be considered matters of public information unless specifically excepted by law or applicable rule or regulation.

Very truly yours,

DONALD DAWSON
Director of Investigations
By: A. Miller
ARIANA MILLER
Supervisor

LJC/AM/nbm
Enclosure
CERTIFIED MAIL – RRR
cc: Judith A. Eisen, Esq.
Garfunkel Wild, P.C.
111 Great Neck Road
Great Neck, NY 11021

C201406

VOTE AND ORDER

MEDLINE INDUSTRIES INC.

CALENDAR NO. 27278

NEW YORK STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE
STATE BOARD OF PHARMACY
----------X

IN THE MATTER

of the

Disciplinary Proceeding

against

MEDLINE INDUSTRIES INC.

which is currently registered to operate as a pharmacy wholesaler in the State of New York.
----------X

APPLICATION FOR CONSENT ORDER

CAL. NO. 27278

LARA N. SIMMONS states:

That I am President, Quality Assurance and Regulatory Affairs of **MEDLINE INDUSTRIES INC.**, hereinafter referred to as the Respondent, and make this application on Respondent's behalf.

That on or about February 21, 2007 Respondent was registered to operate as a pharmacy wholesaler in the State of New York, having been issued Registration No. 028250 by the New York State Education Department.

Respondent is currently registered with the New York State Education Department to operate as a pharmacy wholesaler in the State of New York from an address at: 3301 Route 6, Middletown, New York 10940.

Respondent has been charged with one (1) specification of professional misconduct, a copy of which is annexed hereto, made a part hereof, and marked as Exhibit "A". Respondent admits

guilt to the aforesaid specification of professional misconduct, charging it with having been found guilty of improper professional practice or professional misconduct by a duly authorized professional disciplinary agency of another state where the conduct upon which the finding was based would, if committed in New York State, constitute professional misconduct under the laws of New York State (findings of misconduct committed during the period 2008 to 2009 by three separate states which, if committed in New York, would constitute professional misconduct under the Education Law and Commissioner's Regulations).

Respondent hereby agrees to the penalty that it pay a fine in the amount of five thousand dollars ($5,000.00), said fine to be paid by certified or cashier's check, made payable to the order of the New York State Education Department, to be delivered to the Director, Office of Professional Discipline, 1411 Broadway, 10th Floor, New York, New York 10018-3496, within thirty (30) days after the effective date of the Order to be issued in this matter.

Respondent hereby makes this application to the Board of Regents and requests that it be granted.

Respondent understands that in the event that the Board of Regents denies the application, nothing contained herein shall be binding upon it or construed to be an admission of any act of misconduct alleged or charged against it. Such application shall

not be used against it in any way and shall be kept in strict confidence during the pendency of the disciplinary proceeding, and such denial by the Board of Regents shall be without prejudice to the continuance of the disciplinary proceeding and the final determination by the Board of Regents pursuant to the provisions of the Education Law.

Respondent agrees that in the event the Board of Regents grants its application, as set forth herein, an Order may be issued in accordance with the same. Respondent understands that if and when the Board of Regents grants this application, the entire application shall become a matter of public record.

No promises of any kind were made to Respondent. Respondent is making this application of its own free will and accord and not under duress, compulsion, or restraint of any kind or manner.

LARA N. SIMMONS

EXHIBIT "A"

MEDLINE INDUSTRIES INC.

SPECIFICATION OF PROFESSIONAL MISCONDUCT

Respondent is charged with having been found guilty of improper professional practice or professional misconduct by a duly authorized professional disciplinary agency of another state where the conduct upon which the finding was based would, if committed in New York State, constitute professional misconduct under the laws of New York State, within the purview and meaning of New York Education Law section 6509(5)(b), in that:

(a) On or about September 26, 2008, the Department of Health of the State of Florida, a duly authorized disciplinary agency of said state, issued a Final Order against the Respondent (Case No. 2007-11783);

(b) The conduct upon which said Final Order was based was that (1) Respondent failed to provide in a timely manner documents that were requested and (2) Respondent sold or transferred a legend drug to a person who was not authorized under the law of the jurisdiction in which the person received the drug to purchase or possess legend drugs from the Respondent;

(c) Said conduct, if committed in New York, would constitute professional misconduct under Section 6509(13) of the Education Law and Part 63.6(c)(5)

of the Commissioner's Regulations;

(d) On or about May 1, 2008, the Louisiana Board of Wholesale Drug Distributors, a duly authorized disciplinary agency of Louisiana, issued a Consent Order against the Respondent (Administrative Case No. 2008006);

(e) The conduct upon which said Consent Order was based was that Respondent failed to maintain current customer license documents and/or a current customer listing on-site;

(f) Said conduct, if committed in New York, would constitute professional misconduct under Part 63.6(c)(5) of the Commissioner's Regulations;

(g) On or about February 4, 2009, the Wisconsin Pharmacy Examining Board, a duly authorized disciplinary agency of Wisconsin, issued a Final Decision and Order (Case #08-PHM 037);

(h) The conduct upon which said Decision and Order was based was that when Respondent was inspected by the Wisconsin Department of Regulation and Licensing, it was found that certain policies were missing and that it was storing prescription drugs in a warehouse it shared with another company;

(i) Said conduct, if committed in New York, would constitute professional misconduct under Part 63.6(c)(4) of the Commissioner's Regulations and

Title 21, Section 205.50, Code of Federal Regulations (CFR).

NEW YORK STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE
STATE BOARD OF PHARMACY

IN THE MATTER

of the

Disciplinary Proceeding

against

MEDLINE INDUSTRIES INC.

which is currently registered to operate as a pharmacy wholesaler in the State of New York.

APPLICATION FOR CONSENT ORDER

CAL. NO. 27278

The undersigned agree to the above statement and to the proposed penalty based on the terms and conditions thereof.

MEDLINE INDUSTRIES INC.

Dated: 2/14, 2014

Respondent

BY:

Lara N. Simmons, President, Quality Assurance and Regulatory Affairs

Dated: 2/18, 2014

Attorney for Respondent

Dated: 2/27, 2014

Member, State Board of Pharmacy

Dated: 3/6, 2014

Executive Secretary
State Board of Pharmacy

Dated: 4/23, 2014

Director
Office of Professional Discipline

The undersigned, a member of the Board of Regents who has been designated by the Chairman of the Regents Committee on Professional Practice to review this Application for a Consent Order, has reviewed said Application and recommends to the Board of Regents that the Application be granted.

Dated: 5/7, 2014

Member, Board of Regents

:ds

Section 24.7 (b) For individuals served prior to June 20, 1997 with an order of revocation, acceptance of surrender, or denial of an application for restoration or reinstatement by vote of the Board of Regents, at least one year shall have elapsed from the date of such service for the acceptance by the department of a petition to the Board of Regents for restoration of a license or certificate, except that a period of time during which the license was suspended during the pendency of the discipline proceeding may reduce the one-year waiting period. For individuals served on or after June 20, 1997 with an with an order of revocation, acceptance of surrender, or denial of an application for restoration or reinstatement by vote of the Board of Regents, at least three years shall have elapsed from the date of such service for the acceptance by the department of a petition to the Board of Regents for restoration of a license or certificate, except that a period of time during which the license was suspended during the pendency of the discipline proceeding may reduce the three-year waiting period. This section shall not apply to restoration of licenses which have been temporarily surrendered pursuant to Education Law, section 6510-b, or Public Health Law, section 230(13).

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	01/06/2021	IL	Libertyville	Lake

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
A-2020-0054	Ohio Board of Pharmacy

Reason/Charge
Customer License

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Ohio Board of Pharmacy / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. distribution center at 1501 Harris Rd Libertyville, IL 60048 (OH License #01-1985050) entered into a settlement agreement with the Ohio Board of Pharmacy for the sale of dangerous drugs to an unlicensed entity. Medline maintained a current and valid DEA license on file rather than the correct Terminal Distributor Dangerous Drugs license (TDDD). The facility's TDDD license expired at the time of the sale. Case resolved via Settlement Agreement effective 01/06/2021.

Corrective Actions:
Medline updated its customer license requirements for Ohio customers. Medline completed a review of all Ohio customers to verify the correct license type was on file and implemented increased verification checks of Ohio licenses.

Original Signature (electronic, copies or stamps not accepted)

6/30/26
Date

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE No. A-2020-0054
I-2019-0972-B

Medline Industries, Inc.
c/o Willis Ingalls
1501 Harris Road
Libertyville, IL 60048

License No. 01-1985050

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Medline Industries, Inc. for the purpose of resolving all issues between the parties relating to the Board investigation of a selling dangerous drugs to an unlicensed entity. Together, the Board and Medline Industries are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Medline Industries, LLC, has an active WDDD license with the Board under license number 01-1985050, which lists Willis Ingalls as the Responsible Person.

FACTS

1. The Board initiated an investigation of Medline Industries, WDDD license number 01-1985050, related to the sale of dangerous drugs to an unlicensed entity.

2. On or about December 3, 2020, the Board sent a Notice of Opportunity for Hearing to Medline Industries, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Medline Industries neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated December 3, 2020, however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Medline Industries agrees to pay to the Board a monetary penalty the amount of $250.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. Medline Industries agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. Medline Industries agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Medline Industries of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Medline Industries by the Board and will NOT discharge Medline Industries from any obligation under the terms of this Agreement.

6. Medline Industries agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. Medline Industries understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Medline Industries will operate.

9. Medline Industries expressly waives its opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Willis A. Ingalls — 1-5-21

Willis Ingalls, on behalf of,
Medline Industries, Respondent — **Date of Signature**

Attorney for Respondent (if applicable) — **Date of Signature**

Jennifer M. Rudell, RPh — 1-6-2021

Jennifer M. Rudell, RPh, President,
State of Ohio Board of Pharmacy — **Date of Signature**

1-6-2021

Henry Appel, Ohio Assistant Attorney General — **Date of Signature**

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	06/28/2021	IL	Libertyville	Lake

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
21-L-0048	Alabama Board of Pharmacy

Reason/Charge
Discipline incurred in another jurisdiction

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Alabama Board of Pharmacy / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

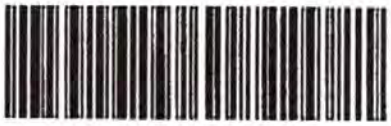
Medline Industries, Inc. distribution center at 1501 Harris Rd Libertyville, IL 60048 (AL Non-Resident Permit #193718) was fined for discipline incurred in another jurisdiction (OH A-2020-0054).

Original Signature (electronic, copies or stamps not accepted)

07/30/20
Date

Alabama Board of Pharmacy
111 Village Street
Birmingham AL 35242

USPS CERTIFIED MAIL



9414 8118 9876 5809 1318 98

MEDLINE INDUSTRIES, INC.
1501 HARRIS ROAD
LIBERTYVILLE IL 60048



$5.86 US POSTAGE
FIRST-CLASS
Jun 28 2021
Mailed from ZIP 35242
1 oz First-Class Mail Letter

11923275



062S0012913542

FO - 21-L-0048 193718

DocuSign Envelope ID: 7F8AA924-F79F-4BC6-A7E1-B16F9D238852

THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	
MEDLINE INDUSTRIES, INC.	)	BOARD OF PHARMACY
	)	
Wholesale Distributor Permit No. 193718	)	CASE NO: 21-L-0048

FINAL ORDER

On June 15, 2021, this cause came before the Alabama State Board of Pharmacy (hereinafter also referred to as the "Board"), on a Complaint against Medline Industries, Inc. (hereinafter also referred to as the "Respondent"). Evidence having been adduced thereon, the Board has determined that the following Findings of Fact and Conclusions of Law are supported by the preponderant weight of evidence and law.

Findings of Fact

1. The Respondent is a wholesale distributor permitted by this Board under Permit No. 193718. (Board Exhibit One)

2. The Respondent was properly notified of the charges on March 9, 2021. The Respondent did not appear at the scheduled hearing before the Board and was not represented by counsel at such hearing. (Board Exhibit One and Two)

3. The Respondent made no objection to the timeliness of the Notice of Hearing or the specificity of the Statement of Charges.

4. The Respondent violated Board Rules 680-X-2.23, 680-X-2.23(3), 680-X-2.23(3)(k)(1), 680-X-2.23(3)(k)(2), and 680-X-2.23(3)(k)(3) and Code of Alabama (1975), § 34-23-32 based upon Respondent's underlying conduct in its entry into a Settlement Agreement with the State of Ohio Board of Pharmacy dated January 6, 2021 (Attached) in which discipline was

DocuSign Envelope ID: 7F8AA924-F79F-4BC6-A7E1-B16F9D238852

imposed. In that Settlement Agreement, Respondent admitted that the State of Ohio Board of Pharmacy had evidence sufficient to sustain the allegations that Respondent made five (5) illegal sales of dangerous drugs to Columbus Podiatry & Surgery, Inc.

Conclusions of Law

1. The Alabama State Board of Pharmacy has jurisdiction of this cause pursuant to Code of Alabama (1975), § 34-23-,32 Code of Alabama (1975), § 34-23-92(12), and Code of Alabama (1975), § 41-22-12.

2. The Respondent was properly notified of the charges, failed to appear and was not represented by counsel at the administrative hearing. The Respondent did not contest the matter in any manner.

3. The Respondent made no objection to the timeliness of the Notice of Hearing or the specificity of the Statement of Charges.

4. The Respondent is due to be fined $500.00 in that it is guilty of violating Board Rules 680-X-2.23, 680-X-2.23(3), 680-X-2.23(3)(k)(1), 680-X-2.23(3)(k)(2), and 680-X-2.23(3)(k)(3) and Code of Alabama (1975), § 34-23-32 in regard to its conduct involving illegal sales of dangerous drugs which resulted in discipline/Settlement Agreement dated January 6, 2021 with the State of Ohio Board of Pharmacy.

ORDER

In accordance with the foregoing Findings of Fact and Conclusions of Law, it is hereby ORDERED as follows:

DocuSign Envelope ID: 7F8AA924-F79F-4BC6-A7E1-B16F9D238852

1. The Respondent is guilty as charged in Count One as contained in the Statement of Charges and Notice of Hearing and is hereby fined a total of Five Hundred ($500.00) Dollars.

2. The disciplinary fine of Five Hundred ($500.00) Dollars is due and payable to the Board within thirty (30) days of the date of this Final Order.

DONE and ORDERED, this 28th day of June, 2021.

Brenda R. Denson, Pharm.D., President
Alabama State Board of Pharmacy

Copies to:
Medline Industries, Inc.
Ms. Donna C. Yeatman, R. Ph., Executive Secretary
Mr. James S. Ward, Esq.
Mr. James F. Hampton, Esq.
Mr. Vance L. Alexander, Esq.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	11/01/2022	OH	West Jefferson	Madison

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
A-2022-0333	Ohio Board of Pharmacy

Reason/Charge
Customer Licenses

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Ohio Board of Pharmacy / Medline Industries, LP	Administrative Action

Name of Business/Industry/Entity
Medline Industries, LP

Provide explanation below:

Medline Industries, LP distribution center at 1040 Enterprise Parkway South, West Jefferson, OH 43162 (OH License #01-30000190) entered a settlement agreement with the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file instead of the correct Terminal Distributor Dangerous Drugs license (TDDD). The TDDD license was added in May 2022. During the period of July 2021 to March 2022, the customer's TDDD license lapsed, and Medline shipped the customer product under the valid practitioner license. Case resolved via Settlement Agreement effective 11/01/2022.

Corrective Actions:
Medline updated customer licensing requirements for Ohio customers following OH Case # A-2020-0054. The shipments in this matter occurred while Medline was in the process of reviewing and updating all Ohio customer licenses. Medline licensing staff were also provided with additional training on Ohio license requirements.

Original Signature (electronic, copies or stamps not accepted)

07/30/26
Date

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. A-2022-0333
I-2022-0624

Medline Industries, LP
c/o James Eveland
1040 Enterprise Parkway South
West Jefferson, OH 43162

License No. 01-30000190

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Medline Industries, LP, for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of dangerous drugs to an unlicensed entity. Together, the Board and Medline Industries, LP are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Medline Industries, LP, is a licensed Distributor of Dangerous Drug, License No. 01-30000190, which lists James Eveland, as the Responsible Person.

FACTS

1. The Board initiated an investigation of Medline Industries, LP, Distributor of Dangerous Drugs License No. 01-30000190, related to Medline Industries, LP's illegal sales of dangerous drugs to an unlicensed entity.

2. On or about September 28, 2022, the Board sent a Notice of Opportunity for Hearing to Medline Industries, LP, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Medline Industries, LP neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated September 28, 2022; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Medline Industries, LP agrees to pay to the Board a monetary penalty in the amount of $1,125.00. This fine will be attached to your license record and must be paid no later than 180 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. The Board hereby imposes a written reprimand on Medline Industries, LP's WDDD license, number 01-30000190.

5. Medline Industries, LP agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

6. Medline Industries, LP agrees to comply with all federal and state requirements related to Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Medline Industries, LP of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Medline Industries, LP by the Board and will NOT discharge Medline Industries, LP from any obligation under the terms of this Agreement.

7. Medline Industries, LP agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. Medline Industries, LP understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Medline Industries, LP will operate.

10. Medline Industries, LP waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

14. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

15. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

James Eveland, on behalf of,
Medline Industries, LP, Respondent

10-25-2022
Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

Shawn Wilt, RPh, President,
State of Ohio Board of Pharmacy

11.1.2022
Date of Signature

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	12/19/2022	FL	Miami	Miami-Dade

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
A-2022-0333	FL DBPR- Div. of Drugs, Devices, and Cosmetics

Reason/Charge
Customer Licenses, Record Keeping

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
FL DBPR / Medline Industries, LP	Administrative Action

Name of Business/Industry/Entity
Medline Industries, LP

Provide explanation below:

Medline Industries, LP distribution center at 9670 NW 112th Ave, Miami, FL 33178 (FL WDD# #2220297) entered a settlement agreement for alleged violations of selling prescription drugs to an unauthorized recipient and failure to maintain proper records. Medline accepted a physician license for a customer which should have maintained a Healthcare Clinic Establishment Permit. The recordkeeping allegation related to missing NDC numbers on outbound packing slips and invoices.

Corrective Actions:
Medline updated customer licensing requirements for Florida customers and completed an extensive review of all FL customer licenses to verify the correct license type was on file. Medline determined the missing NDC number on the packing slip and invoice occurred due to an internal system error. The error was limited to DSCSA exempt products, i.e. IV fluids. A fix was implemented to correct the issue.



Original Signature (electronic, copies or stamps not accepted)

07/30/26

Date

FILED
Department of Business and Professional Regulation
Senior Deputy Agency Clerk
CLERK: Brandon Nichols
Date: 12/21/2022
File #: 2022-09829

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner,

v. **Case No.: 2022-031132**

MEDLINE INDUSTRIES, LP,

Respondent,

_____/

FINAL ORDER

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics ("the Department"), in accordance with the provisions of Section 120.57(4), Florida Statutes, hereby enters this Final Order incorporating and adopting, *in toto*, the Settlement Agreement entered into between Medline Industries, LP, and the Department, attached hereto and incorporated by reference.

This Final Order is effective on the date it is filed with the Agency Clerk of the Department as indicated on this Final Order.

DONE and ORDERED this 19th day of December, 2022 in Tallahassee, Florida.

MELANIE S. GRIFFIN, SECRETARY

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

By: _____
Walter S. Copeland, Director
Division of Drugs, Devices, and Cosmetics

Prepared by:

Anthony Coniglio
DDC Chief Attorney

NOTICE OF RIGHT TO APPEAL

Unless expressly waived, any party adversely affected by this Final Order may seek judicial review by filing an original Notice of Appeal with the Clerk of the Department of Business & Professional Regulation, and a copy of the Notice, accompanied by the filing fees prescribed by law, with the clerk of the appropriate District Court of Appeal within 30 days of the effective date of this order, in accordance with Florida Rule of Appellate Procedure 9.110, and Section 120.68, Florida Statutes.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of this Final Order has been provided by regular US mail to: Corporation Service Company, Registered Agent for Medline Industries, LP, 1201 Hays Street, Tallahassee, Florida 32301 on this 21st day of December, 2022.

By: Brandon M. Nichols
Agency Clerk's Office

RECEIVED
[illegible] 09 2022
DRUGS, DEVICES AND COSMETICS

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner, **Case No.: 2022-031132**

v.

MEDLINE INDUSTRIES, LP,

Respondent.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the above-named parties hereby enter into this Settlement Agreement (hereinafter, "this agreement") as disposition of the alleged violations described in the Notice of Violation in case number 2022-031132 (hereinafter, "the allegations"). The terms herein become effective upon rendition of the final order, which shall incorporate this agreement.

The State of Florida, Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (hereinafter, "the Department") is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 20.165 and Chapter 499, Florida Statutes.

STIPULATED FACTS

1. Medline Industries, LP (hereinafter, "Respondent") is permitted by the Department as a prescription drug wholesale distributor, having been issued permit number 22:20297.

2. Respondent's address of record is 9670 Northwest 112th Avenue, Miami, Florida 33178.

3. Respondent was issued a Notice of Violation on October 26, 2022, alleging that it committed certain violations of Chapter 499, Florida Statutes, and the administrative rules adopted

pursuant thereto.

CONCLUSIONS OF LAW

4. Respondent, by and through its undersigned agent, admits that it is subject to the applicable provisions of Chapter 499, Florida Statutes, and the relevant jurisdiction of the Department.

5. Respondent neither admits nor denies the allegations in the Notice of Violation issued in case number 2022-031132, but enters into this agreement for the purpose of resolving the issues raised by the Department.

SETTLEMENT TERMS

6. Respondent affirms that it is currently in compliance with Chapter 499, Florida Statutes.

7. Respondent agrees to pay a settlement amount of six thousand dollars ($6,000.00). **Payment of the settlement amount shall be made only by corporate check, cashier's check, or money order to the Professional Regulation Trust Fund, and shall be remitted to The Florida Department of Business & Professional Regulation, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, Florida 32399-1047, Attention: Kimberley Johnson, Senior Legal Assistant**. Respondent acknowledges that payment is enclosed with this agreement. The payment and execution of this agreement by Respondent are absolute conditions precedent to the Department's execution of this agreement.

8. The acceptance of this agreement constitutes disciplinary action within the meaning of Section 499.066, Florida Statutes and Rule 61N-1.024, Florida Administrative Code.

STANDARD PROVISIONS

9. It is expressly understood that a violation of the terms of this agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary action may be taken.

10. The parties agree that this agreement will be incorporated into a final order that will be filed with the Department agency clerk and will be a public document. The final order will contain no material terms other than those in this agreement. **The final order shall operate to close case number 2022-031132. The final order shall be the final disposition in this proceeding and shall constitute final agency action with respect thereto.**

11. Respondent expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this agreement and the final order in which this agreement is incorporated, provided the final order does not conflict with this agreement.

12. Each party waives the right to seek any attorney's fees or costs from the other party in connection with this proceeding.

13. This agreement may be executed in any number of counterparts including, without limitation, telecopies and facsimile transmission copies, all of which together shall constitute a single document.

14. The parties agree that this agreement represents a fair, appropriate, and reasonable resolution to, and final disposition of, all disputes and matters made subject hereof.

15. The terms and provisions of this agreement are severable and, if any term or provision is declared or deemed void, invalid, illegal, or otherwise unenforceable, then all remaining terms and provisions shall remain in full force and effect.

16. It is expressly understood that this agreement is subject to approval of the Division of Drugs, Devices, and Cosmetics, and has no force or effect until the Division accepts this

agreement and adopts it in a final order.

17. The signatories hereto are vested with the authority to execute this agreement on behalf of their respective principals and, as duly designated representatives, to fully bind such principals.

MEDLINE INDUSTRIES, LP,

By: _____

Name: Daniel Stevens

Title: Manager Regulatory Affairs

Date: 11/18/2022

FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION DIVISION OF DRUGS, DEVICES, AND COSMETICS,

By: _____

Name: Walter Copeland

Title: Division Director

Date: 12.19.2022

Prepared by:

Anthony Coniglio
DDC Legal Chief
Division of Drugs, Devices, and Cosmetics

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
2601 Blair Stone Road
Tallahassee, Florida 32399
www.MyFloridaLicense.com

US POSTAGE PITNEY BOWES
ZIP 32399 $ 001.44⁰
02 4W
0000375736 DEC 21 2022

Corporation Service Company
Registered Agent for Medline Industries, LP
1201 Hays Street
Tallahassee, Florida 32301

Case No: 2022-031132 (Final Order)

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	07/25/2023	OH/IN	See Below	See Below

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
A-2022-0307; A-2022-0184	Ohio Board of Pharmacy

Reason/Charge
Customer Licenses

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Ohio Board of Pharmacy / Medline Industries, LP	Administrative Action

Name of Business/Industry/Entity
Medline Industries, LP

Provide explanation below:

Medline Industries, LP distribution centers at 1040 Enterprise Parkway South, West Jefferson, OH 43162 (OH License #01-30000190) and 251 Hilton Drive. Jeffersonville, IN 47130 (OH License #01-30000158) entered settlement agreements with the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. The sales occurred between July 2021 and January 2022. Medline maintained valid practitioner licenses on file for each customer instead of the correct d sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file instead of the correct Terminal Distributor Dangerous Drugs license (TDDD). Cases resolved via Settlement Agreement effective 07/19/2023 and 07/25/2023.

Corrective Actions:
Medline updated customer licensing requirements for Ohio customers following OH Case # A-2020-0054. The shipments in this matter occurred between July 2021 and January 2022 while Medline was in the process of reviewing and updating all Ohio customer licenses.

Locations:
1040 Enterprise Parkway South, West Jefferson, OH 43162 (Madison County)
251 Hilton Drive, Jeffersonville, IN 47130 (Clark County)

Original Signature (electronic, copies or stamps not accepted)

07/13/26
Date

STATE OF OHIO
BOARD OF PHARMACY

July 19, 2023

Medline Industries, LP
c/o James Eveland
1040 Enterprise Parkway South
West Jefferson, OH 43162

Re: Settlement Agreement
License No. 01-30000190

Dear Mercy Primary Care Portage,

Enclosed you will find your Settlement Agreement with the State of Ohio Board of Pharmacy. This document is signed and effective as of July 19, 2023. If you have any questions or concerns, please do not hesitate to contact the Board of Pharmacy and ask to speak with someone in the Legal Department.

Sincerely,

Jennifer Nelson

Jennifer Nelson
Legal Administrative Assistant

Enclosure: July 19, 2023 Settlement Agreement with the State of Ohio Board of Pharmacy

CMRRR: 9414 7118 9956 2233 7395 37

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. A-2022-0307
I-2022-0168

Medline Industries, LP
c/o James Eveland
1040 Enterprise Parkway South
West Jefferson, OH 43162

License No. 01-30000190

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Medline Industries, LP, for the purpose of resolving all issues between the parties relating to the Board investigation of sales of dangerous drugs to unlicensed entities. Together, the Board and Medline Industries, LP are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Medline Industries, LP, is a licensed Distributor of Dangerous Drug, License No. 01-30000190, which lists James Eveland, as the Responsible Person.

FACTS

1. The Board initiated an investigation of Medline Industries, LP, Distributor of Dangerous Drugs License No. 01-30000190, related to Medline Industries, LP's illegal sales of dangerous drugs to an unlicensed entity.

2. On or about 11/16/2022, the Board sent a Notice of Opportunity for Hearing to Medline Industries, LP, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Medline Industries, LP neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated 11/16/2022; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Medline Industries, LP agrees to pay to the Board a monetary penalty in the amount of $875.00.00. This fine will be attached to your license record and must be paid no later than 60 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. The Board hereby imposes a written reprimand on Medline Industries, LP 's WDDD license, number 01-30000190.

5. Medline Industries, LP agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

6. Medline Industries, LP agrees to comply with all federal and state requirements related to Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Medline Industries, LP of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Medline Industries, LP by the Board and will NOT discharge Medline Industries, LP from any obligation under the terms of this Agreement.

7. Medline Industries, LP agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. Medline Industries, LP understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Medline Industries, LP will operate.

10. Medline Industries, LP waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

14. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

15. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

James Eveland, on behalf of, Medline Industries, LP, Respondent	7-11-23 Date of Signature
Attorney for Respondent (if applicable)	Date of Signature
Trina Buettner, RPh, President, State of Ohio Board of Pharmacy	07.19.2023 Date of Signature

STATE OF OHIO
BOARD OF PHARMACY

July 25, 2023

Medline Industries
c/o Filomena Kropiweic
251 Hilton Dr.
Jeffersonville, IN 47130

Re: Settlement Agreement
License No. 0130000158

Dear Medline Industries,

Enclosed you will find your Settlement Agreement with the State of Ohio Board of Pharmacy. This document is signed and effective as of July 25, 2023. If you have any questions or concerns, please do not hesitate to contact the Board of Pharmacy and ask to speak with someone in the Legal Department.

Sincerely,

Jennifer Nelson

Jennifer Nelson
Legal Administrative Assistant

Enclosure: July 25, 2023 Settlement Agreement with the State of Ohio Board of Pharmacy

CMRRR: 9414 7118 9956 2027 4018 31

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE No. A-2022-0184
I-2021-1908

Medline Industries
c/o Filomena Kropiweic
251 Hilton Drive
Jeffersonville, IN 47130

License No. 01-30000158

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Medline Industries, for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of dangerous drugs to an unlicensed entity. Together, the Board and Medline Industries are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Medline Industries is a licensed Distributor of Dangerous Drug, License No. 01-30000158, which lists Filomena Kropiweic as the Responsible Person.

FACTS

1. The Board initiated an investigation of Medline Industries, Distributor of Dangerous Drugs License No. 01-30000158, related to Medline Industries' illegal sales of dangerous drugs to an unlicensed entity.

2. On or about April 25, 2023, the Board sent a Notice of Opportunity for Hearing to Medline Industries, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Medline Industries neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated April 25, 2023; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Medline Industries agrees to pay to the Board a monetary penalty in the amount of $750.00. This fine will be attached to your license record and must be paid no later than 60 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. The Board hereby imposes a written reprimand on Medline Industries' WDDD license, number 01-30000158.

5. Medline Industries agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

6. Medline Industries agrees to comply with all federal and state requirements related to Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Medline Industries of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Medline Industries by the Board and will NOT discharge Medline Industries from any obligation under the terms of this Agreement.

7. Medline Industries agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. Medline Industries understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Medline Industries will operate.

10. Medline Industries waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

14. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

15. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Filomena Kropiweic

Filomena Kropiweic, on behalf of,
Medline Industries, Respondent

06-29-2023

Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

07.25.2023

Trina Buettner, RPh, President,
State of Ohio Board of Pharmacy

Date of Signature

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	12/21/2023	HI	Kapolei	Honolulu

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
PHA 2023-9-L	Hawaii Department of Commerce and Consumer Affairs

Reason/Charge
Discipline incurred in another jurisdiction

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
HI DCCA / Medline Industries, LP	Administrative Action

Name of Business/Industry/Entity
Medline Industries, LP

Provide explanation below:

Medline Industries, LP distribution center at 2341 Lauwiliwili St, Kapolei, HI 96707 (HI #) entered a Settlement Agreement for discipline incurred in another jurisdiction (OH A-2022-0333, OH A-2022-0307, OH A-2022-0184, and FL 2022-031132)

Original Signature (electronic, copies or stamps not accepted)

07/30/26
Date

IVY Y. E. KIM 9609
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 S. Beretania Street, 9th Floor
Honolulu, Hawaii 96813
Telephone: (808) 586-2660
E-mail: ikim@dcca.hawaii.gov

Attorney for Department of Commerce
and Consumer Affairs

2023 DEC 15 A 11:07
DEPT. OF COMMERCE AND CONSUMER AFFAIRS
2023 DEC 29 P 12:37
HEARINGS OFFICE

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Wholesale Prescription Drug Distributor License of MEDLINE INDUSTRIES, L.P., Respondent.	PHA 2023-9-L SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" – "3"

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney and Respondent MEDLINE INDUSTRIES, L.P. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was licensed as a wholesale prescription drug distributor by the Board of Pharmacy (hereinafter the "Board") under the license number PWD-193. The license was issued on or about May 16, 2022. The license will expire or forfeit on or about December 31, 2023, unless timely renewed.

2. Respondent's mailing address for purposes of this action is 2341 Lauwiliwili Street, Kapolei, Hawaii 96707.

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

3. On or about December 19, 2022, the Florida Department of Business & Professional Regulation (hereinafter "Department") issued a Final Order adopting the Settlement Agreement entered into between Respondent and the Department in Case No. 2022-031132 (hereinafter the "Florida Final Order"). The Florida Final Order was based on Respondent's alleged selling of prescription drugs to an unauthorized recipient, failure to maintain records, and failure to provide required documentation to customers. The Florida Final Order is attached hereto as Exhibit "1".

4. On or about July 19, 2023, Respondent and State of Ohio Board of Pharmacy entered into a Settlement Agreement in Case No. A-2022-0307, I-2022-0168, related to Respondent's illegal sales of dangerous drugs to an unlicensed entity. The Settlement Agreement is attached hereto as Exhibit "2".

5. On or about July 25, 2023, Respondent and State of Ohio Board of Pharmacy entered into a Settlement Agreement in Case No. A-2022-0184, I-2021-1908, related to Respondent's illegal sales of dangerous drugs to an unlicensed entity. The Settlement Agreement is attached hereto as Exhibit "3".

6. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes (hereinafter "HRS") § 436B-19(13) (disciplinary action by another state or federal agency).

7. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing, and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent, being at all times relevant herein licensed as a wholesale prescription drug distributor by the Board, acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the license and administrative fines, if the foregoing allegations are proven at hearing. Respondent further understands that RICO enters into this Settlement Agreement and agrees to the specific terms contained in this Settlement Agreement, based upon Respondent's representations made herein.

5. Respondent represents that Exhibits "1" – "3" are true and correct copies of the purported Florida Final Order and Settlement Agreements with the Ohio Board of Pharmacy.

6. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this Settlement Agreement may be grounds for further disciplinary action under HRS Chapters 436B and 461.

7. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's license.

8. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

9. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2023-9-L.

10. Respondent understands that this Settlement Agreement may be subject to reporting requirements.

11. Respondent understands this Settlement Agreement is public record pursuant to HRS Chapter 92F.

12. Respondent acknowledges that upon tis approval, this Settlement Agreement constitutes disciplinary action.

C. TERMS OF SETTLEMENT:

1. Administrative Fine. Respondent agrees to pay an administrative fine in the amount of TWO THOUSAND TWO HUNDRED FIFTY AND NO/100 DOLLARS ($2,250.00). Payment shall be made by **cashier's check or money order made payable to "DCCA – Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn.: Ivy Y. E. Kim, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph C.1. above, Respondent's license shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of licensure to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new license until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become licensed again, Respondent must apply to the Board for a new license pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible Further Sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board

may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of pharmacies in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5., C.6., and C.7. below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent, nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion, or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion, or promise made by RICO or any of its agents, employees, representatives, or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

[Remainder of this page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below. Each signatory to this Settlement Agreement hereby represents and warrants that he/she is authorized to execute and deliver this Settlement Agreement in the capacity shown below.

DATED: Northfield (City), IL (State), 09/07/2023 (Date).

MEDLINE INDUSTRIES, L.P.
Respondent

By: _____
(Signature)

Daniel Stevens
(Print Name)

Its Manager Regulatory Affairs
(Print Title)

DATED: Honolulu, Hawaii, 10/11/2023.

_____
IVY Y. E. KIM
Attorney for Department of Commerce
and Consumer Affairs

IN THE MATTER OF THE WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR LICENSE OF MEDLINE INDUSTRIES, L.P.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" – "3"; RICO CASE NO. PHA 2023-9-L.

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

ALANNA ISOBE
Chair

December 21, 2023
DATE

PATRICK ADAMS
Vice Chair

MARK BROWN

CATALINA CROSS

Kent Kikuchi
KENT KIKUCHI

BRANDON RABANG

SHERI TOKUMARU

PVL 11/09/22

POWER OF ATTORNEY

MEDLINE INDUSTRIES, LP, an Illinois limited partnership, having a principal place of business at 3 Lakes Drive, Northfield, Illinois, 60093 (the "Company"), herewith authorize and entrust a Power of Attorney to DANIEL A. STEVENS, United States citizen, Manager Regulatory Affairs, with permanent residence at 4217 Arlington Avenue, Sacramento, CA 95820 with full signatory rights on behalf of the Company as follows:

To be our true and lawful Agent with as full as legally necessary powers to submit, execute and prosecute applications in the name of the Company, for permits, registrations and other governmental authorizations, relating in any way to the quality assurance, quality control, regulatory, warehousing and sterilizing functions of the Company, and to represent the Company and take all necessary actions in legal matters and all other matters towards all third parties and all public authorities, federal, state or municipal, and towards all other divisions, subdivisions, departments, units or all secretariats of the above, relating in any way to the quality assurance, quality control, regulatory, warehousing and sterilizing functions of the Company.

This power of Attorney is valid until revoked in writing by the Company.

Dated: October 11, 2022

Medline Industries, LP

By: Mozart GP, LLC
Its: General Partner

By: _____
Name: Alexander M. Liberman
Title: Assistant Secretary

ACKNOWLEDGEMENT

STATE OF ILLINOIS
COUNTY OF COOK

This instrument was acknowledged before me on October 11, 2022 by Alexander M. Liberman, as Assistant Secretary of Mozart GP, LLC, as General Partner of Medline Industries, LP.

_____
(Signature of Notary Public)

(Seal)

"OFFICIAL SEAL"
BARBARA BYCHOWSKI
NOTARY PUBLIC, STATE OF ILLINOIS
MY COMMISSION EXPIRES 8/29/2025

4G

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10)

Section 1: General Information

Facility Name: Medline Industries, LP

Physical Address: 18601 Christopher Way, Ste 100

City: Lathrop State: CA Zip: 95330

Mailing Address (if different from physical address): Three Lakes Drive, #3D

City: Northfield State: IL Zip: 60093

Telephone: 209-858-1033 Website: https://www.medline.com/

Name of Designated Representative (DR): Marqual Devon Mitchell

Licensing Company Email: ralicensing@medline.com DR Email: mrmitchell@medline.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☒ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ [a]Medical Products (medical devices, equipment, supplies, gases)	☐ Reverse Distributor
☒ Wholesalers		☒ Warehouse
☒ Veterinarians	☐ Others:	☐ Retail pharmacy wholesale distributor
☒ Others: Assisted Living, Nursing Homes, Surgical Centers		☐ Others:

Section 2: ONLY COMPLETE THIS SECTION IF THE COMPANY IS WHOLESALING [a]Medical Products (medical devices, equipment, supplies and gases). Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? This facility has not received any discipline. See Attachment 1 for corporate discipline history.	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Section 4: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Pfizer, Inc.
Address: 66 Hudson Blvd E City: New York State: NY Zip: 10001

Name: ICU Medical Inc.
Address: 951 Calle Amanecer City: San Clemente State: CA Zip: 92673

Name: Baxter Healthcare Inc.
Address: One Baxter Parkway City: Deerfield State: IL Zip: 60015

Name: B Braun Medline Inc.
Address: 824 12th Avenue City: Bethlehem State: PA Zip: 18018

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): Medline Inc.
Corporation Name: Attachment 2
Mailing Address: 3 Lakes Drive
City: Northfield State: IL Zip: 60093
Telephone: 847-949-5500 Email: ralicensing@medline.com
Contact Person Name: Daniel Stevens 916-292-0005

Date of SEC Registration: 12/17/2025 | SEC Registration Number: 0002046386 | Stock Exchange Symbol: MDLN

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 8: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 9: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		X
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 10: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** Attachment 2	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** Attachment 3	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** Attachment 4	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) Attachment 5	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** Attachment 6	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** Attachment 7	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale [a]Medical Products (medical devices, equipment, supplies, gases). (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Products (medical devices, equipment, supplies, gases), supply a copy of proof of insurance (NAC 639.6957).** The Medical Products wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). Attachment 8	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 9)				
• **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20NRS%20639.500%20-%20Effective%2001.07.2026%20-%20Wholesaler%20-%20Post%20on%201.26.26.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Medline Industries, LP

Facility Name

Daniel Stevens

Print Name of Authorized Person Submitting Application

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

07/14/2026

Date

Board Use Only	Date Received: 8/18/26	Amount: $1000 CK 2935597

Attachment 2

Medline Industries, LP

FEIN: 36-2596612
An Illinois Limited Partnership

Contact Information:

Three Lakes Drive
Attn: RA Licensing – 3D
Northfield, IL 60093
Ralicensing@medline.com
847-949-5500

Partners:

Partner	General or Limited	Business Address	% of Ownership	FEIN
Medline Borrower, LP	Limited	Three Lakes Drive, Northfield, IL 60093	100%	87-2530238
Mozart GP, LLC	General	Three Lakes Drive, Northfield, IL 60093	0%	87-2508203

Officers of General Partner - Mozart GP, LLC:

Name	Title	Home Address	SSN	DOB
James M. Boyle	Chief Executive Officer	[redacted]		
Stephen L. Miller	Chief Operating Officer			
Michael B. Drazin	Chief Financial Officer			
Alexander M. Liberman	General Counsel, Secretary			

Attachment 2 (cont.)

Medline Inc.

FEIN: IL 33-185288

Contact Information:
3 Lakes Drive
Attn: RA Licensing – 3D
Northfield, IL 60093
Ralicensing@medline.com
847-949-5500

Officers and Directors:
Information as of 07/09/2026

Officers

Name	Title
James M. Boyle	Chief Executive Officer
Michael B. Drazin	Chief Financial Officer
Stephen L. Miller*	Chief Operating Officer
Alexander M. Liberman	Chief Legal Officer
Douglas P. Golwas	Chief Commercial Officer
Christopher P. Shryock	Chief Human Resources Officer
Amanda Hutton Laabs	Chief Product Officer
Jessi Corcoran	Chief Accounting Officer
William J. Abrams	Executive Vice President, Supply Chain Solutions

*On July 7, 2026, Stephen L. Miller, Chief Operating Officer of Medline Inc. (the "Company"), notified the Company that he would retire from his role, effective August 30, 2026/ The Company is launching a search for his successor.

Directors

Name	Title
Charles N. Mills	Non-Executive Chair of the Board
Andrew J. Mills	Director
Anushka M. Sunder	Director
Jacob D. Best	Director
James M. Boyle	Director
Joseph P. Baratta	Director
Patrick J. Healy	Director
Richard A. Galanti	Director
Robert R. Schmidt	Director
Stephen H. Wise	Director
Thomas W. Sweet	Director
Todd N. Bluedorn	Director

Attachment 3

Medline Inc.
Top Four Shareholders

Medline Inc.
Medline Inc. is a U.S. publicly traded company trading under the ticker symbol MDLN on Nasdaq. Medline Inc. publicly reports beneficial holders of 5% or more of its outstanding securities ("significant stockholders") in its filings with the U.S. Securities and Exchange Commission ("SEC"), which are available at www.sec.gov/edgar/browse/?CIK=2046386. Medline Inc. reports this information in accordance with SEC rules, including in reliance on public reporting of ownership by its significant stockholders.

Top Four Shareholders of Medline Inc. as of May 4, 2026

Name of Beneficial Owner	Combined Voting Power
Mozart HoldCo, Inc.[1]	17.8%
Blackstone[2]	14.2%
Carlyle[3]	14.2%
H&F[4]	14.2%

[1] Mozart HoldCo, Inc. is an entity that is owned directly and/or indirectly by members of the Mills Family and trusts for their benefit.
[2] "Blackstone" refers to certain entities and/or funds associated with Blackstone Inc.
[3] "Carlyle" refers to certain entities and/or funds associated with The Carlyle Group Inc.
[4] "H&F" refers to certain entities and/or funds associated with Hellman & Friedman LLC

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "MEDLINE INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRD DAY OF APRIL, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "MEDLINE INC." WAS INCORPORATED ON THE SIXTH DAY OF NOVEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5143163 8300

SR# 20261572157

Authentication: 203550646

Date: 04-03-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	MEDLINE INDUSTRIES, LP
Entity No.:	202126300006
Registration Date:	09/16/2021
Entity Type:	Limited Partnership - Out of State
Formed In:	ILLINOIS
Status:	Active

The above referenced entity is active on the Secretary of State's records and is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of March 04, 2026.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 429547128

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

Attachment 4

CSC

www.cscglobal.com

CSC- Wilmington

251 Little Falls Drive
Wilmington, DE 19808
800-927-9800
302-636-5454 (Fax)

Matter# 92490
Project Id :

Order# 5562990-4
Order Date 03/03/2026

Entity Name:	MEDLINE INDUSTRIES, LP
Jurisdiction:	CA - Secretary Of State
Request for:	Certificate of Status
Result:	Document Retrieved

Ordered by JOANNE WARE (LICENSING) at MEDLINE INDUSTRIES, LP

Thank you for using CSC. For real-time 24 hour access to the status of any order placed with CSC, access our website at www.cscglobal.com.

If you have any questions concerning this order or CSCGlobal, please feel free to contact us.

Renee Patterson
Renee.Patterson@cscglobal.com

The responsibility for verification of the files and determination of the information therein lies with the filing officer; we accept no liability for errors or omissions.

Attachment 7

Renewal License

Wholesale Drug Permit

CALIFORNIA STATE BOARD OF PHARMA
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
(916) 518-3100

License No. WLS 8076
Receipt No. 00203235

Valid Until: 3/1/2027

MEDLINE INDUSTRIES, LP
18601 CHRISTOPHER WAY STE 100
LATHROP, CA 95330

In accordance with the provisions of section 4160 of the Business and Professions Code, the firm name hereon is issued a Wholesale Drug Permit.

This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) manager, vice president of operations, or designated representative-in-charge.

This permit is valid only at the address shown.

The official status of this license can be verified at www.pharmacy.ca.gov

---- NON-TRANSFERABLE ----- POST IN PUBLIC VIEW -----

FORM WPHWLS (09/30/19) W

MEDLINE INDUSTRIES, LP
18601 CHRISTOPHER WAY STE 100
LATHROP, CA 95330
10563

BOARD OF PHARMACY
2720 GATEWAY OAKS DR, SUITE 100
SACRAMENTO, CA 95833

Attachment 8

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
06/22/2026

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

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

PRODUCER MARSH USA LLC. 155 N. WACKER, SUITE 1200 CHICAGO, IL 60661 CN101705524-Stnd-GAWUP-26-27 USA	**CONTACT NAME:** Medline Industries, LP **PHONE (A/C, No, Ext):** **FAX (A/C, No):** **E-MAIL ADDRESS:** riskmanagement@medline.com
INSURED Medline Industries, LP 3 Lakes Dr Northfield, IL 60093	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** Safety National Casualty Corporation — 15105 **INSURER B :** Endurance Assurance Corporation — 11551 **INSURER C :** See Acord 101 for Carrier Participation **INSURER D :** **INSURER E :** **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** CHI-008956355-45 **REVISION NUMBER:** 80

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X **COMMERCIAL GENERAL LIABILITY** CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			GL 4065036	07/01/2026	07/01/2027	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ $ $ $ $ $	2,000,000 2,000,000 10,000 2,000,000 4,000,000 SEE BELOW
A	**AUTOMOBILE LIABILITY** X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			CA 6675933	07/01/2026	07/01/2027	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $	2,000,000
B	X **UMBRELLA LIAB** X OCCUR **EXCESS LIAB** CLAIMS-MADE DED X RETENTION $ 10,000			ELD10004065213	07/01/2026	07/01/2027	EACH OCCURRENCE AGGREGATE	$ $	10,000,000 10,000,000
A A	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: Y If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		LDS 4065032 (AOS) PS 4065034 (WI)	07/01/2026 07/01/2026	07/01/2027 07/01/2027	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $	1,000,000 1,000,000 1,000,000
C	Products/Completed Operations Liability			LSR-PCO-00678-26	07/01/2026	07/01/2027	Limit		2,000,000

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

Re: C42 - 3446 Highway 51 N Southaven, MS 38672. C40- 81 Campanelli Dr, Uxbridge, MA 01569.

SIR applies per policy terms & conditions. The products/completed operations policy evidenced above is subject to self-insured retentions for various perils covered.

Evidence of Insurance.

CERTIFICATE HOLDER

Medline Industries, LP
3 Lakes Dr.
Northfield, IL 60093

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Marsh USA Inc.

© 1988-2016 ACORD CORPORATION. All rights reserved.

AGENCY CUSTOMER ID: CN101705524

LOC #: Chicago

ACORD®

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC.	Medline Industries, LP 3 Lakes Dr Northfield, IL 60093
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

LOCATION ADDRESS CITY STATE ZIP CODE

B01 1 Medline Pl. Mundelein Illinois 60060
B04 1160 S Northpoint Blvd S. Waukegan Illinois 60085
B04 1710 S Lakeside Dr. Waukegan Illinois 60085
B04 1170 S Northpoint Blvd S. Waukegan Illinois 60085
B06 1 Medline Dr. Wilmer Texas 75172
B11 21111 E 36th Dr. Aurora Colorado 80011
B18 1062 Fasken Blvd. Laredo Texas 78045
B22 9670 NW 112 Ave. Medley Florida 33178
B24 8001 SW 47th St. Oklahoma City Oklahoma 73179
B25 1401 N Universal Ave. Kansas City Missouri 64120
B27 92 SE 223rd Ave. Gresham Oregon 97030
B28 735 County Rd 4 E. Prattville Alabama 36067
B29 13115 Brockton Lane N. Rogers Minnesota 55374
B30 1900 Meadowville Technology Parkway. Chester Virginia 23836
B31 500 Sharkey Dr. Maumelle Arkansas 72113
B34 9051 King St. Anchorage Alaska 99518
B36 1989 Transit Way. Brockport New York 14420
B44 2325 W Louise Ave. Manteca California 95337
B45 1119 W Middlesex Ave Bldg 4. Port Reading New Jersey 07064
B48 36445 Van Born Road, Suite 200 Romulus Michigan 48174
B49 42500 Winchester Rd. Temecula California 92590
B56 190 Medline Drive, Suite 200. Richmond Hill Georgia 31324
B66 2700 E. Imperial Highway Lynwood California 90262
B80 2341 Lauwiliwili St. Suite 107 Kapolei Hawaii 96707
B82 9103 Riverside Parkway Lithia Springs Georgia 30122
C02 2200 Cornerstone Parkway. Grayslake Illinois 60030
C03 1500 Medline Pl. McDonough Georgia 30253
C05 1062 Old Dixie Highway. Auburndale Florida 33823
C09 1960 W Miro Way. Rialto California 92376
C32 29895 US Hwy 90 Bus. Katy Texas 77494
C37 5000 Premier Parkway. St. Peters Missouri 63376
C40 81 Campanelli Dr. Uxbridge Massachusetts 01569
C41 1040 Enterprise Parkway South. West Jefferson Ohio 43162
C42 3446 Highway 51 N. Southaven Mississippi 38672
C46 5701 Promontory Parkway, Suite 100 Tracy California 95377
C47 239 Belvidere Rd. Perryville Maryland 21903
C50 8787 W Buckeye Ave. Tolleson Arizona 85353
C54 494 State Route 416. Montgomery New York 12549
C57 5511 W Ten Rd. Mebane North Carolina 27302
C59 2100 Industrial Park Road Hammond Louisiana 70401
C71 264 S 5750 W. Salt Lake City Utah 84104
C75 3770 Hogum Bay Rd NE. Lacey Washington 98516
C89 251 Hilton Dr. Jeffersonville Indiana 47130
RCH - Hartland, WI 700 W North Shore Dr. Hartland Wisconsin 53029
D46 - Lathrop, CA 18601 Christopher Way Ste 100. Lathrop California 95330
MXC - SPT 16415 Cosmos St. Moreno Valley California 92551
ANGIO 10 Glen Falls Technical Park. Glen Falls New York 12801
E22 600 Derby Ave West Haven Connecticut 06516
E23 3835 John Wall Dr Madison Wisconsin 53704

© 2008 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: CN101705524

LOC #: Chicago

ACORD®

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC.	Medline Industries, LP 3 Lakes Dr Northfield, IL 60093
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

E26 1390 Sparrows Point Blvd Ste700 Edgemere Maryland 21219
LRD 12001 General Milton Dr. Laredo Texas 78045

© 2008 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Medline Industries, LP — MDEG License # (if applicable): Pending

Physical Address: 18601 Christopher Way, Ste 100

City: Lathrop — State: CA — Zip: 95330

Mailing Address (if different from physical address): Three Lakes Drive, #3D

City: Northfield — State: IL — Zip: 60093

Telephone: 209-858-1033 — Website: www.medline.com

Licensing Company Email: ralicensing@medline.com

Section 2: Personal Information

First: Marqual — Middle: Devon — Last: Mitchell

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

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

Mailing Address: [redacted]

City: Elk Grove — State: CA — Z: [redacted]

Telephon: [redacted] — Email: mrmitchell@medline.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Amos P. Godby High School		06/99 - 05/03	
Address	**City**	**State**	**Zip**
1717 W Tharpe St	Tallahassee	FL	32304
Diploma/Degree obtained, if any			
Diploma			

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

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2016 - Present	[redacted]	Elk Grove	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Medline Industries, LP			06/22 - Present	
Business Address		**City**	**State**	**Zip**
18601 Christopher Way, Ste 100		Lathrop	CA	95330
Phone	**Title**		**Number of Employed Hours**	
209-858-1033	Dir Operations		8,000+	
Description of Duties				
Oversee the facility to ensure proper receiving, distribution, storage, shipping and dispensing of prescription drugs and medical devices. Manage multiple team members to ensure proper record keeping, inventory, storage, & product security				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

7/21/2026
Date

I, Marqual D Mitchell, **certify that as the MDEG Administrator for**

Medline Industries, LP,

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

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

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

Marqual D Mitchell
Print Name (First, Last)

Marqual D Mitchell
Original Signature (electronic, copies or stamps not accepted)

7/21/2026
Date

Board Use Only	Date Received: 8/18/26

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Medline Industries, LP

Pharmacy/Wholesaler License # (if applicable): Pending

Physical Address: 18601 Christopher Way, Ste 100

City: Lathrop State: CA Zip: 95330

Mailing Address (if different from physical address): Three Lakes Drive, #3D

City: Northfield State: IL Zip: 60093

Telephone: 209-858-1033 Website: www.medline.com

Licensing Company Email: ralicensing@medline.com

Section 2: Personal Information

First: Marqual Middle: Devon Last: Mitchell

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

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

Mailing Addres: [redacted]

City: Elk Grove State: CA Zip: [redacted]

Telephor: [redacted] Email: mrmitchell@medline.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Amos P. Godby High School		06/99 - 05/03	
Address	**City**	**State**	**Zip**
1717 W Tharpe St	Tallahassee	FL	32304
Diploma/Degree obtained, if any			
Diploma			

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

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2016 - Present	[redacted]	Elk Grove	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Medline Industries, LP			06/22 - Present	
Business Address		**City**	**State**	**Zip**
18601 Christopher Way, Ste 100		Lathrop	CA	95330
Phone	**Title**		**Number of Employed Hours**	
209-858-1033	Dir Operations		8,000+	
Description of Duties				
Oversee the facility to ensure proper receiving, distribution, storage, shipping and dispensing of prescription drugs and medical devices. Manage multiple team members to ensure proper record keeping, inventory, storage, & product security				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

7/21/2026
Date

I, Marqual D Mitchell, **certify that as the designated representative for**

Medline Industries, LP,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MDM I am at least 21 years of age;
3. MDM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MDM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MDM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MDM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MDM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Marqual D Mitchell
Print Name (First, Last)

Marqual Mitchell
Original Signature (electronic, copies or stamps not accepted)

7/21/2026
Date

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

Marqual D Mitchell

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/21/2026

Date

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

State of Illinois, ss. County of Cook

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

Original Signature

7/21/2026

Date

Subscribed and Sworn to before me this 21st day of July 2026.

Notary Public Signature

OFFICIAL SEAL
KIARA LEE ROSADO
Notary Public, State of Illinois
Commission No. 1012800
My Commission Expires
June 30, 2029

(Seal)

Attachment 6

MED - HCM Employee Roster - Copy

Location Address - Country
Division
Location OPS- Lathrop, CA D46
Organizations
Include Subordinate Orgar No

Employee ID	Name	Job Title	Division	Company	Hire Date	Location	Worker Type
[redacted]	Catherine Cooley	Warehouse Operator Operations	Operations	Medline Industries, LP	7/7/2008	OPS- Lathrop, CA D46	Employee
	Tony Phatame	Sr Supv Warehouse	Operations	Medline Industries, LP	8/31/2009	OPS- Lathrop, CA D46	Employee
	Markizes Linsay	Trainer Branch	Operations	Medline Industries, LP	9/8/2015	OPS- Lathrop, CA D46	Employee
	Jordan Cavazos	Supv Warehouse	Operations	Medline Industries, LP	10/11/2016	OPS- Lathrop, CA D46	Employee
	Benny Quilantang	Warehouse Operator Operations	Operations	Medline Industries, LP	7/10/2017	OPS- Lathrop, CA D46	Employee
	C Miller	Warehouse Operator Operations	Operations	Medline Industries, LP	7/17/2017	OPS- Lathrop, CA D46	Employee
	Michael Prevost	Supv Warehouse	Operations	Medline Industries, LP	8/7/2017	OPS- Lathrop, CA D46	Employee
	Clara Estrella Islas	Warehouse Clerk Operations	Operations	Medline Industries, LP	3/19/2018	OPS- Lathrop, CA D46	Employee
	Tiffany Messinger Nunley	Inventory Control Ld Operations	Operations	Medline Industries, LP	4/2/2018	OPS- Lathrop, CA D46	Employee
	Daniel Nieto	Inventory Coord Operations	Operations	Medline Industries, LP	4/23/2018	OPS- Lathrop, CA D46	Employee
	Eric Mao	Warehouse Operator Operations	Operations	Medline Industries, LP	7/26/2018	OPS- Lathrop, CA D46	Employee
	Jenina Dela Cruz	Supv Warehouse	Operations	Medline Industries, LP	8/22/2019	OPS- Lathrop, CA D46	Employee
	Roumail William	Warehouse Operator Operations	Operations	Medline Industries, LP	1/14/2019	OPS- Lathrop, CA D46	Employee
	Nadia Suarez (On Leave)	Warehouse Operator Operations	Operations	Medline Industries, LP	8/22/2019	OPS- Lathrop, CA D46	Employee
	Maria Bustos	Warehouse Operator Operations	Operations	Medline Industries, LP	7/16/2020	OPS- Lathrop, CA D46	Employee
	Jose Avalos	Trainer Branch	Operations	Medline Industries, LP	8/27/2020	OPS- Lathrop, CA D46	Employee
	Ko Rena Nunnally	Warehouse Operator Operations	Operations	Medline Industries, LP	8/27/2020	OPS- Lathrop, CA D46	Employee
	Victor Verdin	Warehouse Ld Operations	Operations	Medline Industries, LP	11/19/2020	OPS- Lathrop, CA D46	Employee
	Paul Martinez	Warehouse Operator Operations	Operations	Medline Industries, LP	2/2/2021	OPS- Lathrop, CA D46	Employee
	Eduardo Magana	Warehouse Operator Operations	Operations	Medline Industries, LP	3/2/2021	OPS- Lathrop, CA D46	Employee
	Habraham Herrera	Warehouse Ld Operations	Operations	Medline Industries, LP	5/4/2021	OPS- Lathrop, CA D46	Employee
	Angelica Rubalcaba (On Leave)	Warehouse Operator Operations	Operations	Medline Industries, LP	5/27/2021	OPS- Lathrop, CA D46	Employee
	Eugenia Abibo	Warehouse Ld Operations	Operations	Medline Industries, LP	6/28/2021	OPS- Lathrop, CA D46	Employee
	Efrain Quintero	Trainer Branch	Operations	Medline Industries, LP	9/9/2021	OPS- Lathrop, CA D46	Employee
	Issiah Lopez	Warehouse Operator Operations	Operations	Medline Industries, LP	8/31/2021	OPS- Lathrop, CA D46	Employee
	Emily Cedillo (On Leave)	Warehouse Operator Operations	Operations	Medline Industries, LP	9/28/2021	OPS- Lathrop, CA D46	Employee
	Edna Estrada	Warehouse Operator Operations	Operations	Medline Industries, LP	9/2/2021	OPS- Lathrop, CA D46	Employee
	Alexis Gonzalez	Supv Warehouse	Operations	Medline Industries, LP	9/9/2021	OPS- Lathrop, CA D46	Employee
	Eric Alop	Warehouse Operator Operations	Operations	Medline Industries, LP	9/16/2021	OPS- Lathrop, CA D46	Employee
	Alondra Ramirez	Inventory Coord Sr	Operations	Medline Industries, LP	9/28/2021	OPS- Lathrop, CA D46	Employee
	Ryan Aranas	Warehouse Operator Operations	Operations	Medline Industries, LP	10/7/2021	OPS- Lathrop, CA D46	Employee
	Destinee Lopez	Warehouse Operator Operations	Operations	Medline Industries, LP	11/12/2024	OPS- Lathrop, CA D46	Employee
	Andrew Thongthirak	Warehouse Operator Operations	Operations	Medline Industries, LP	10/14/2021	OPS- Lathrop, CA D46	Employee
	Jenny Zhou	Inventory Coord Operations	Operations	Medline Industries, LP	10/26/2021	OPS- Lathrop, CA D46	Employee
	Samantha Estrella Islas	Inventory Coord Operations	Operations	Medline Industries, LP	11/2/2021	OPS- Lathrop, CA D46	Employee
	Tamara Estrella Islas	Warehouse Operator Operations	Operations	Medline Industries, LP	11/2/2021	OPS- Lathrop, CA D46	Employee
	John Palaruan	Warehouse Ld Operations	Operations	Medline Industries, LP	11/2/2021	OPS- Lathrop, CA D46	Employee
	Gregory Xaythavone	Warehouse Operator Operations	Operations	Medline Industries, LP	11/18/2021	OPS- Lathrop, CA D46	Employee
	Sera Corona	Warehouse Operator Operations	Operations	Medline Industries, LP	12/16/2021	OPS- Lathrop, CA D46	Employee
	Priscilla Santacruz	Warehouse Operator Operations	Operations	Medline Industries, LP	2/1/2022	OPS- Lathrop, CA D46	Employee
	Mayra Sierra Suarez (On Leave)	Warehouse Operator Operations	Operations	Medline Industries, LP	2/10/2022	OPS- Lathrop, CA D46	Employee
	Noel Quezada	Warehouse Operator Operations	Operations	Medline Industries, LP	2/1/2022	OPS- Lathrop, CA D46	Employee
	Gilberto Medina	Warehouse Operator Operations	Operations	Medline Industries, LP	5/11/2026	OPS- Lathrop, CA D46	Employee
	Rafael Cerda	Warehouse Ld Operations	Operations	Medline Industries, LP	5/31/2022	OPS- Lathrop, CA D46	Employee
	Marqual Mitchell	Dir Operations	Operations	Medline Industries, LP	6/13/2022	OPS- Lathrop, CA D46	Employee
	Jorge Ordonez Rivas	Warehouse Operator Operations	Operations	Medline Industries, LP	5/11/2026	OPS- Lathrop, CA D46	Employee
	Huy Pham	Warehouse Operator Operations	Operations	Medline Industries, LP	7/12/2022	OPS- Lathrop, CA D46	Employee
	Adoree Tan	Warehouse Operator Operations	Operations	Medline Industries, LP	7/12/2022	OPS- Lathrop, CA D46	Employee
	Nam Nguyen-Hoang	Warehouse Operator Operations	Operations	Medline Industries, LP	7/26/2022	OPS- Lathrop, CA D46	Employee
	Joseph Galvan	Supv Training Branch	Operations	Medline Industries, LP	8/16/2022	OPS- Lathrop, CA D46	Employee
	Adam Frazier	Mgr Warehouse	Operations	Medline Industries, LP	8/22/2022	OPS- Lathrop, CA D46	Employee
	Maurice Ball	Sr Supv Warehouse	Operations	Medline Industries, LP	8/18/2022	OPS- Lathrop, CA D46	Employee
	Juan Martinez	Trainer Branch	Operations	Medline Industries, LP	9/13/2022	OPS- Lathrop, CA D46	Employee

Attachment 6 (cont.)

764200	Alejandra Ramirez	Warehouse Operator Operations	Operations	Medline Industries, LP	6/22/2026	OPS- Lathrop, CA D46	Employee
764707	Gabriel Avila	Warehouse Operator Operations	Operations	Medline Industries, LP	11/15/2022	OPS- Lathrop, CA D46	Employee
764710	Cindy Torres	Warehouse Operator Operations	Operations	Medline Industries, LP	11/3/2022	OPS- Lathrop, CA D46	Employee
768234	Juan Cerda	HR Generalist	Human Resources	Medline Industries, LP	3/6/2023	OPS- Lathrop, CA D46	Employee
769299	Neal Adams	Supv Warehouse	Operations	Medline Industries, LP	4/4/2023	OPS- Lathrop, CA D46	Employee
770318	Johnaton Ing	Warehouse Operator Operations	Operations	Medline Industries, LP	4/17/2023	OPS- Lathrop, CA D46	Employee
770525	Stephanie Arroyo Valentin	Warehouse Operator Operations	Operations	Medline Industries, LP	5/1/2023	OPS- Lathrop, CA D46	Employee
770793	Maria Pimentel	Warehouse Operator Operations	Operations	Medline Industries, LP	5/16/2023	OPS- Lathrop, CA D46	Employee
771294	Mauricio Pina Cardona	Warehouse Operator Operations	Operations	Medline Industries, LP	5/18/2023	OPS- Lathrop, CA D46	Employee
773590	Juan Aguirre	Warehouse Operator Operations	Operations	Medline Industries, LP	7/25/2023	OPS- Lathrop, CA D46	Employee
775674	Carlos Camilo	Warehouse Operator Operations	Operations	Medline Industries, LP	9/25/2023	OPS- Lathrop, CA D46	Employee
775792	Romy Pisigan	Trainer Branch	Operations	Medline Industries, LP	9/19/2023	OPS- Lathrop, CA D46	Employee
778577	Alvin Cara	Warehouse Operator Operations	Operations	Medline Industries, LP	1/9/2024	OPS- Lathrop, CA D46	Employee
778580	Joanna Atmosfera	Warehouse Operator Operations	Operations	Medline Industries, LP	12/19/2023	OPS- Lathrop, CA D46	Employee
779880	George Tapia	Maintenance Tech II	Operations	Medline Industries, LP	2/26/2024	OPS- Lathrop, CA D46	Employee
780157	Tiana Ahumada (On Leave)	Office Coord	Operations	Medline Industries, LP	2/13/2024	OPS- Lathrop, CA D46	Employee
781006	Tony Flores	Warehouse Operator Operations	Operations	Medline Industries, LP	4/1/2024	OPS- Lathrop, CA D46	Employee
782405	Lizbeth Garcia	Warehouse Operator Operations	Operations	Medline Industries, LP	5/21/2024	OPS- Lathrop, CA D46	Employee
782591	Richard Porras	Warehouse Operator Operations	Operations	Medline Industries, LP	5/21/2024	OPS- Lathrop, CA D46	Employee
782637	Ariel De Jesus	Warehouse Operator Operations	Operations	Medline Industries, LP	5/14/2024	OPS- Lathrop, CA D46	Employee
783270	Manuel Garcia	Warehouse Operator Operations	Operations	Medline Industries, LP	6/18/2024	OPS- Lathrop, CA D46	Employee
783730	Constantino Garcia	Warehouse Operator Operations	Operations	Medline Industries, LP	7/9/2024	OPS- Lathrop, CA D46	Employee
132303	Miguel Velazquez Andrade	Warehouse Operator Operations	Operations	Medline Industries, LP	7/29/2024	OPS- Lathrop, CA D46	Employee
132523	Leopoldo Rojas (On Leave)	Warehouse Operator Operations	Operations	Medline Industries, LP	8/12/2024	OPS- Lathrop, CA D46	Employee
134143	Mirka Cisneros Caballero	Warehouse Operator Operations	Operations	Medline Industries, LP	8/20/2024	OPS- Lathrop, CA D46	Employee
134147	Humberto Salazar	Warehouse Operator Operations	Operations	Medline Industries, LP	8/20/2024	OPS- Lathrop, CA D46	Employee
134144	Maria chavez	Warehouse Operator Operations	Operations	Medline Industries, LP	8/27/2024	OPS- Lathrop, CA D46	Employee
134492	Kevin Krupa	Warehouse Operator Operations	Operations	Medline Industries, LP	8/27/2024	OPS- Lathrop, CA D46	Employee
134145	Daniel Garcia	Warehouse Operator Operations	Operations	Medline Industries, LP	9/3/2024	OPS- Lathrop, CA D46	Employee
134382	Jeremiah Varao	Warehouse Operator Operations	Operations	Medline Industries, LP	8/27/2024	OPS- Lathrop, CA D46	Employee
134490	Edward Aguilar	Warehouse Operator Operations	Operations	Medline Industries, LP	9/3/2024	OPS- Lathrop, CA D46	Employee
134498	Kevin Lim	Warehouse Operator Operations	Operations	Medline Industries, LP	8/26/2024	OPS- Lathrop, CA D46	Employee
134380	Nestor Arteaga	Warehouse Operator Operations	Operations	Medline Industries, LP	9/3/2024	OPS- Lathrop, CA D46	Employee
134859	Bryan Bruno	Warehouse Operator Operations	Operations	Medline Industries, LP	9/3/2024	OPS- Lathrop, CA D46	Employee
134858	Anthony Bagalayos	Warehouse Operator Operations	Operations	Medline Industries, LP	9/17/2024	OPS- Lathrop, CA D46	Employee
135222	Luis Torres	Warehouse Operator Operations	Operations	Medline Industries, LP	9/17/2024	OPS- Lathrop, CA D46	Employee
135752	Aries jan Cara	Warehouse Operator Operations	Operations	Medline Industries, LP	9/17/2024	OPS- Lathrop, CA D46	Employee
136954	Clay Toreno	Warehouse Operator Operations	Operations	Medline Industries, LP	10/8/2024	OPS- Lathrop, CA D46	Employee
136802	Jacob Lagudas	Warehouse Operator Operations	Operations	Medline Industries, LP	10/22/2024	OPS- Lathrop, CA D46	Employee
136955	Erik Cisneros	Warehouse Operator Operations	Operations	Medline Industries, LP	10/8/2024	OPS- Lathrop, CA D46	Employee
137668	Mark Caro	Warehouse Operator Operations	Operations	Medline Industries, LP	10/15/2024	OPS- Lathrop, CA D46	Employee
137525	Jonique Echevarria	Warehouse Operator Operations	Operations	Medline Industries, LP	10/15/2024	OPS- Lathrop, CA D46	Employee
137289	Angelica Gonzalez	Warehouse Operator Operations	Operations	Medline Industries, LP	10/22/2024	OPS- Lathrop, CA D46	Employee
138315	Nou Yang	Warehouse Operator Operations	Operations	Medline Industries, LP	10/29/2024	OPS- Lathrop, CA D46	Employee
138255	Anuradha Chaganti	Sr Analyst Financial	Finance	Medline Industries, LP	11/11/2024	OPS- Lathrop, CA D46	Employee
138728	Sharie Tenorio (On Leave)	Warehouse Operator Operations	Operations	Medline Industries, LP	11/19/2024	OPS- Lathrop, CA D46	Employee
138724	Shawnia Long	Warehouse Operator Operations	Operations	Medline Industries, LP	11/12/2024	OPS- Lathrop, CA D46	Employee
138733	Allan Manalac	Warehouse Operator Operations	Operations	Medline Industries, LP	11/26/2024	OPS- Lathrop, CA D46	Employee
139686	Alfredo Salazar	Warehouse Operator Operations	Operations	Medline Industries, LP	11/26/2024	OPS- Lathrop, CA D46	Employee
139798	Jonathan Valerio (On Leave)	Warehouse Operator Operations	Operations	Medline Industries, LP	12/3/2024	OPS- Lathrop, CA D46	Employee

Attachment 6 (cont.)

140557	ANDREA INIGUEZ	Warehouse Operator Operations	Operations	Medline Industries, LP	12/17/2024 OPS- Lathrop, CA D46	Employee
143274	Diana Cisneros	Warehouse Operator Operations	Operations	Medline Industries, LP	2/17/2025 OPS- Lathrop, CA D46	Employee
143406	Ramiro Padilla	Janitor Operations	Operations	Medline Industries, LP	3/4/2025 OPS- Lathrop, CA D46	Employee
144595	Tiffany Amataga	Warehouse Operator Operations	Operations	Medline Industries, LP	3/13/2025 OPS- Lathrop, CA D46	Employee
144614	Moises Silva	Warehouse Operator Operations	Operations	Medline Industries, LP	3/13/2025 OPS- Lathrop, CA D46	Employee
144572	Trey Jones	Warehouse Operator Operations	Operations	Medline Industries, LP	3/25/2025 OPS- Lathrop, CA D46	Employee
144985	Eric Goodwin	Janitor Operations	Operations	Medline Industries, LP	3/25/2025 OPS- Lathrop, CA D46	Employee
146455	Chris Luna	Warehouse Operator Operations	Operations	Medline Industries, LP	4/14/2025 OPS- Lathrop, CA D46	Employee
147060	Cristian Lopez	Warehouse Operator Operations	Operations	Medline Industries, LP	4/21/2025 OPS- Lathrop, CA D46	Employee
147375	Hanalei Kalua-Adams	Warehouse Operator Operations	Operations	Medline Industries, LP	4/21/2025 OPS- Lathrop, CA D46	Employee
147589	Jannet Richard	Warehouse Operator Operations	Operations	Medline Industries, LP	5/5/2025 OPS- Lathrop, CA D46	Employee
147503	Ricky Gallegos	Warehouse Operator Operations	Operations	Medline Industries, LP	5/5/2025 OPS- Lathrop, CA D46	Employee
147643	Atish Chand	Warehouse Operator Operations	Operations	Medline Industries, LP	5/5/2025 OPS- Lathrop, CA D46	Employee
148420	Phany choub	Warehouse Operator Operations	Operations	Medline Industries, LP	5/19/2025 OPS- Lathrop, CA D46	Employee
148202	PHILLIP HERNANDEZ	Warehouse Operator Operations	Operations	Medline Industries, LP	5/19/2025 OPS- Lathrop, CA D46	Employee
148869	Gloria Suarez (On Leave)	Warehouse Operator Operations	Operations	Medline Industries, LP	6/2/2025 OPS- Lathrop, CA D46	Employee
148867	Jonathan Rodriguez	Warehouse Operator Operations	Operations	Medline Industries, LP	6/2/2025 OPS- Lathrop, CA D46	Employee
148868	Embry Allen	Warehouse Operator Operations	Operations	Medline Industries, LP	6/2/2025 OPS- Lathrop, CA D46	Employee
153835	Princeza Gutierrez	Warehouse Operator Operations	Operations	Medline Industries, LP	10/6/2025 OPS- Lathrop, CA D46	Employee
153815	Dacian Caracol	Warehouse Operator Operations	Operations	Medline Industries, LP	10/20/2025 OPS- Lathrop, CA D46	Employee
153816	Aaron Garcia Huerta	Warehouse Operator Operations	Operations	Medline Industries, LP	10/6/2025 OPS- Lathrop, CA D46	Employee
157589	Mhy Vea	Warehouse Operator Operations	Operations	Medline Industries, LP	12/1/2025 OPS- Lathrop, CA D46	Employee
160169	Mathew Atencion	Warehouse Operator Operations	Operations	Medline Industries, LP	2/2/2026 OPS- Lathrop, CA D46	Employee
162653	MARK SOTO	Warehouse Operator Operations	Operations	Medline Industries, LP	2/23/2026 OPS- Lathrop, CA D46	Employee
162682	Victor Petrochilos	Maintenance Tech I	Operations	Medline Industries, LP	3/9/2026 OPS- Lathrop, CA D46	Employee
164772	Jesus Nungaray	Warehouse Operator Operations	Operations	Medline Industries, LP	3/30/2026 OPS- Lathrop, CA D46	Employee
164779	marqais Tolentino	Warehouse Operator Operations	Operations	Medline Industries, LP	3/23/2026 OPS- Lathrop, CA D46	Employee
164771	Tallis Lymuel	Warehouse Operator Operations	Operations	Medline Industries, LP	3/23/2026 OPS- Lathrop, CA D46	Employee
164780	Aliyah Meza	Warehouse Operator Operations	Operations	Medline Industries, LP	3/23/2026 OPS- Lathrop, CA D46	Employee
164776	Jacob Hernandez	Warehouse Operator Operations	Operations	Medline Industries, LP	3/23/2026 OPS- Lathrop, CA D46	Employee
164769	TRAVIS MILLIGAN	Warehouse Operator Operations	Operations	Medline Industries, LP	3/23/2026 OPS- Lathrop, CA D46	Employee
164770	Alejandro Nuno	Warehouse Operator Operations	Operations	Medline Industries, LP	3/23/2026 OPS- Lathrop, CA D46	Employee
164785	Daniel Ruelas	Warehouse Operator Operations	Operations	Medline Industries, LP	3/30/2026 OPS- Lathrop, CA D46	Employee
164789	NICOLE JACKSON	Warehouse Operator Operations	Operations	Medline Industries, LP	4/6/2026 OPS- Lathrop, CA D46	Employee
164774	Angel Lopez Ochoa	Warehouse Operator Operations	Operations	Medline Industries, LP	3/30/2026 OPS- Lathrop, CA D46	Employee
164791	Alysah Palacios	Warehouse Operator Operations	Operations	Medline Industries, LP	3/30/2026 OPS- Lathrop, CA D46	Employee
164787	David Preston	Warehouse Operator Operations	Operations	Medline Industries, LP	4/6/2026 OPS- Lathrop, CA D46	Employee
164773	Dannie Carr	Warehouse Operator Operations	Operations	Medline Industries, LP	3/30/2026 OPS- Lathrop, CA D46	Employee
164786	Manuel Pulido	Warehouse Operator Operations	Operations	Medline Industries, LP	3/30/2026 OPS- Lathrop, CA D46	Employee
165298	Karla Lopez Arreola	Warehouse Operator Operations	Operations	Medline Industries, LP	3/30/2026 OPS- Lathrop, CA D46	Employee
165294	Angel Madrigal	Warehouse Operator Operations	Operations	Medline Industries, LP	4/6/2026 OPS- Lathrop, CA D46	Employee
165297	LANI TOVAR	Warehouse Operator Operations	Operations	Medline Industries, LP	4/6/2026 OPS- Lathrop, CA D46	Employee
165348	Hector Garcia	Warehouse Operator Operations	Operations	Medline Industries, LP	4/6/2026 OPS- Lathrop, CA D46	Employee
165300	Mauricio Muñoz Rodriguez	Warehouse Operator Operations	Operations	Medline Industries, LP	4/6/2026 OPS- Lathrop, CA D46	Employee
165665	Krystal Martinez	Janitor Operations	Operations	Medline Industries, LP	4/13/2026 OPS- Lathrop, CA D46	Employee
165296	Reginald Dent	Warehouse Operator Operations	Operations	Medline Industries, LP	4/13/2026 OPS- Lathrop, CA D46	Employee
165350	Aaron Keegan	Warehouse Operator Operations	Operations	Medline Industries, LP	4/13/2026 OPS- Lathrop, CA D46	Employee
165668	Virginia Coker	Warehouse Operator Operations	Operations	Medline Industries, LP	4/13/2026 OPS- Lathrop, CA D46	Employee
166989	Miguel Garcia	Warehouse Operator Operations	Operations	Medline Industries, LP	4/20/2026 OPS- Lathrop, CA D46	Employee

Attachment 6 (cont.)

167085	Henry Hernandez	Warehouse Operator Operations	Operations	Medline Industries, LP	4/27/2026 OPS- Lathrop, CA D46	Employee
167615	Jordan Turner	Warehouse Operator Operations	Operations	Medline Industries, LP	5/4/2026 OPS- Lathrop, CA D46	Employee
168036	Kci Cooper	Warehouse Operator Operations	Operations	Medline Industries, LP	5/4/2026 OPS- Lathrop, CA D46	Employee
167993	Yanni Phan	Warehouse Operator Operations	Operations	Medline Industries, LP	5/11/2026 OPS- Lathrop, CA D46	Employee
167741	Jose Gamino	Warehouse Operator Operations	Operations	Medline Industries, LP	6/1/2026 OPS- Lathrop, CA D46	Employee
168991	Angel Munguia	Warehouse Operator Operations	Operations	Medline Industries, LP	6/1/2026 OPS- Lathrop, CA D46	Employee
167740	Jesus Ramirez	Warehouse Operator Operations	Operations	Medline Industries, LP	6/1/2026 OPS- Lathrop, CA D46	Employee
168992	Joana Sanchez	Warehouse Operator Operations	Operations	Medline Industries, LP	6/1/2026 OPS- Lathrop, CA D46	Employee
168129	Julian Zuniga	Warehouse Operator Operations	Operations	Medline Industries, LP	6/1/2026 OPS- Lathrop, CA D46	Employee

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 001-43022

Medline Inc.
(Exact name of registrant as specified in its charter)

Delaware	**33-1845288**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3 Lakes Drive Northfield, Illinois	**60093**
(Address of principal executive offices)	(Zip Code)

(847) 949 5500
Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, par value $0.0001 per share	MDLN	Nasdaq Global Select Market

Securities registered pursuant to section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☐ No ☒

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ☐ No ☒

The aggregate market value of the Class A common stock held by non-affiliates of the registrant, based on the closing price of a share of Class A common stock on December 17, 2025, as reported by The Nasdaq Global Select Market on such date was approximately $13.0 billion. The registrant has elected to use December 17, 2025, which was the initial trading date of the registrant's Class A common stock on The Nasdaq Global Select Market, as the calculation date because on June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter) the registrant was a privately held company. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of February 23, 2026, there were 811,647,534 shares of the registrant's Class A common stock and 502,045,878 shares of the registrant's Class B common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement related to its 2026 Annual Meeting of Stockholders to be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year ended December 31, 2025 are incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

Item		Page
	PART I	
1.	Business	7
1A.	Risk Factors	22
1B.	Unresolved Staff Comments	55
1C.	Cybersecurity	55
2.	Properties	56
3.	Legal Proceedings	56
4.	Mine Safety Disclosures	57
	PART II	
5.	Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities	58
6.	[Reserved]	60
7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	61
7A.	Quantitative and Qualitative Disclosures About Market Risk	78
8.	Financial Statements and Supplementary Data	80
9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	135
9A.	Controls and Procedures	135
9B.	Other Information	135
9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	136
	PART III	
10.	Directors, Executive Officers, and Corporate Governance	136
11.	Executive Compensation	136
12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	136
13.	Certain Relationships and Related Transactions, and Director Independence	136
14.	Principal Accountant Fees and Services	136
	PART IV	
15.	Exhibits and Financial Statement Schedule	137
16.	Form 10-K Summary	142
	Signatures	143

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements include all statements that are not historical facts. Words such as "anticipate," "assume," "believe" "contemplate," "continue," "could," "estimate," "expect," "foreseeable," "intend," "may," "plan," "potentially," "predict," "project," "seek," "should," "will," or "would," or similar words or phrases that convey uncertainty of future events or outcomes, are intended to identify forward-looking statements in this Annual Report. These forward-looking statements relate to matters such as our industry, business strategy, costs, and costs savings, impacts of accounting standards and guidance, goals and expectations, market position, future operations, margins, profitability, capital expenditures, liquidity and capital resources, legal matters, trends, and other financial and operating information. The forward-looking statements are based on management's current expectations and are subject to various risks, uncertainty, and changes in circumstances, many of which are beyond our control, that could cause actual results to differ materially. Although we believe that the assumptions underlying the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance, or achievements. Factors that may cause actual results to differ from expected results include those described in Part I, "Item 1A—Risk Factors" and Part II, "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations". The forward-looking statements included in this Annual Report speak only as of the date of this Annual Report or as of the date they are made, as applicable. Except as otherwise required by law, we disclaim any intent or obligation to update any "forward-looking statement" made in this Annual Report to reflect changed assumptions, the occurrence of unanticipated events, or changes to future operating results over time.

INTRODUCTORY NOTE

Medline Inc. was incorporated as a Delaware corporation on November 6, 2024. Prior to the completion of its initial public offering (the "IPO") on December 18, 2025, Medline Inc. undertook certain reorganization transactions (the "Reorganization") such that Medline Inc. is now a holding company, and its sole material assets are its equity interests held directly or indirectly through wholly owned subsidiaries in Medline Holdings, LP ("Medline Holdings"). Following the IPO, Medline Holdings is the predecessor of Medline Inc. for financial reporting purposes. As the general partner of Medline Holdings, Medline Inc. now operates and controls all of the business and affairs of Medline Holdings and, through Medline Holdings and its subsidiaries, conducts its business. The Reorganization lacks economic substance and therefore is accounted for in a manner consistent with a reorganization of entities under common control. As a result, the consolidated financial statements of Medline Inc. recognize the assets and liabilities received in the Reorganization at their historical carrying amounts, as reflected in the historical financial statements of Medline Holdings. Medline Inc. will consolidate Medline Holdings on its consolidated financial statements and record a non-controlling interest related to the Units (as defined herein) held by the Continuing Unitholders (as defined herein) on its consolidated balance sheets and statements of comprehensive income.

Medline Inc. had no significant business transactions or activities prior to the Reorganization, and, as a result, the historical financial information reflects that of Medline Holdings.

Basis of Presentation

The consolidated financial statements and accompanying notes included herein are prepared in accordance with United States generally accepted accounting principles ("GAAP"). The results of businesses acquired or disposed of are included in the consolidated financial statements from the date of the acquisition or up to the date of disposal, respectively. All adjustments, in the opinion of management, necessary to a fair statement of the results for the annual periods presented have been made.

Certain monetary amounts, percentages, and other figures included in this Annual Report have been subject to rounding adjustments. Percentage amounts included in this Annual Report have been calculated, in some cases, not on the basis of such rounded figures, but on the basis of such amounts prior to rounding. For this reason, percentage amounts in this Annual Report may vary from those obtained by performing the same calculations using the figures, on the face of our consolidated financial statements included elsewhere in this Annual Report. Certain other amounts that appear in this Annual Report may not sum due to rounding.

In December 2024, we changed the name of Medline Holdings from Mozart Holdings, LP to Medline Holdings, LP. We will not distinguish between the prior and current name of Medline Holdings and will refer to the current name of Medline Holdings throughout this Annual Report. References in this Annual Report to "Medline," the "Company," "we," "us," and "our" refer (1) prior to the consummation of the IPO, to Medline Holdings, LP and its consolidated subsidiaries and (2) after the IPO to Medline Inc. and its consolidated subsidiaries.

CERTAIN DEFINITIONS

As used in this Annual Report, unless otherwise noted or the context requires otherwise, the following terms have the following meanings:

- "Class A Units" refers to the interests in Medline Holdings called "Class A Units" that were outstanding prior to the Reclassification. In connection with the Reclassification, (i) Class A Units held by Common Unitholders were converted into Common Units and (ii) Class A Units held by Exchanging Class A Unitholders were directly or indirectly exchanged for shares of Class A common stock.
- "Class B Units" refers to the interests in Medline Holdings called "Class B Units" that were outstanding prior to the Reclassification, and does not include CUPI Units. In connection with the Reclassification, (i) Class B Units held by Incentive Unitholders were converted into Incentive Units and (ii) Class B Units held by Exchanging Class B Unitholders were directly or indirectly exchanged for shares of Class A common stock (in the case of vested Class B Units) and/or restricted shares of Class A common stock (in the case of unvested Class B Units).

- "Common Units" refers to the new class of units of Medline Holdings created by the Reclassification and does not include Incentive Units.
- "Common Unitholders" refers to certain pre-IPO holders of Class A Units and/or CUPI Units who hold Common Units following the Reclassification.
- "Incentive Unitholders" refers to certain pre-IPO holders of Class B Units who will hold Incentive Units following the Reclassification, as described under "Organizational Structure."
- "Continuing Unitholders" refers collectively to Common Unitholders and Incentive Unitholders.
- "CUPI Units" refers to the interests in Medline Holdings that were designated as "Catch-Up Class B Units" and outstanding prior to the Reclassification. In connection with the Reclassification, (i) CUPI Units held by Common Unitholders were converted into Common Units and (ii) CUPI Units held by Exchanging CUPI Unitholders were directly or indirectly exchanged for shares of Class A common stock.
- "Designating Stockholder" refers to each of our Principal Stockholders with whom we entered into separate director nomination agreements.
- "Exchanging Class A Unitholder" refers to pre-IPO holders of Class A Units whose Class A Units were directly or indirectly exchanged for shares of Class A common stock following the Reclassification.
- "Exchanging Class B Unitholder" refers to pre-IPO holders of Class B Units whose Class B Units were directly or indirectly exchanged for shares of Class A common stock (in the case of vested Class B Units) and/or restricted shares of Class A common stock (in the case of unvested Class B Units) following the Reclassification.
- "Exchanging CUPI Unitholder" refers to pre-IPO holders of CUPI Units whose CUPI Units were directly or indirectly exchanged for shares of Class A common stock following the Reclassification.
- "Exchanging Unitholders" refers collectively to Exchanging Class A Unitholders, Exchanging CUPI Unitholders, and Exchanging Class B Unitholders.
- "Incentive Units" refers to the new class of units of Medline Holdings created by the reclassification of the Class B Units in the Reclassification. The Incentive Units are "profit interests" having economic characteristics similar to stock appreciation rights and having the right to share in any equity value of Medline Holdings above specified participation thresholds. Vested Incentive Units may be converted to Common Units and be subsequently exchanged for shares of Class A common stock.
- "Principal Stockholders" refers collectively to investment funds associated with Blackstone Inc., The Carlyle Group Inc. and Hellman & Friedman LLC, and members of the Mills family.
- "Reclassification" refers to the reclassification of the partnership interests of Medline Holdings prior to the IPO.
- "Sponsors" refers collectively to Blackstone Inc., The Carlyle Group Inc., and Hellman & Friedman LLC.
- "Units" refers collectively to Common Units and Incentive Units.

Summary of Risk Factors

The following is a summary of the principal factors that make an investment in our securities speculative or risky, all of which are more fully described below. This summary should be read together with the risk factors described under Part I, "Item 1A—Risk Factors" and should not be relied upon as an exhaustive summary of the material risks facing our business. In addition to the following summary, you should consider the information set forth below and the other information contained in this Annual Report before investing in our securities.

- Our global operations are subject to inherent risks that could materially adversely affect our business, results of operations, and financial condition.
- We may be unable to derive fully the anticipated benefits from our existing or future acquisitions, joint ventures, investments, dispositions, or other strategic transactions.
- Consolidation in the healthcare industry could have an adverse effect on our business, results of operations, and financial condition.
- We operate in a highly competitive industry, with accelerating pricing pressure and changes in technology.
- Changes to the U.S. and global healthcare environments may not be favorable to us.
- Increases in shipping costs or service issues with our third-party shippers could harm our business.

- Significant challenges or delays in our sourcing of new products and technologies could have an adverse impact on our long-term success.
- We have concentration in and dependence on certain healthcare provider customers and GPOs.
- Our business and operations depend on the proper functioning of our critical facilities and distribution networks and could be negatively impacted by events outside our control.
- Quality problems and product liability claims have in the past led, and could in the future lead, to recalls or safety alerts, reputational harm, adverse verdicts, or costly settlements, and could have a material adverse effect on our business, results of operations, and financial condition.
- Our failure to establish and maintain Prime Vendor relationships may cause our revenue to decline.
- If we experience increased pressure to maintain or decrease the price of our goods and services and we are unable to reduce our expenses, there may be a material adverse effect on our business, results of operations, and financial condition.
- Any failure by or loss of a third-party manufacturer or supplier or other manufacturing or supply-related impacts could result in delays and increased costs, which may adversely affect our business.
- We rely on the proper function, security, and availability of our information technology systems and data, as well as those of third parties throughout our global supply chain, to operate our business.
- We are subject to extensive and complex laws and governmental regulations and any adverse regulatory action may materially adversely affect our business, results of operations, and financial condition both inside and outside the United States.
- We are subject to complex and rapidly evolving data privacy, security, and data protection laws and regulations and the costs to comply with such laws and regulations or any ineffective compliance efforts with such laws and regulations may adversely impact our business.
- Our use or our third-party service providers' or business partners' use of AI, automated decision-making and machine learning technologies and the evolving regulatory framework in this area may subject us to risks or heightened costs that could adversely affect business, results of operation and financial condition.
- Our failure to comply with laws and regulations relating to reimbursement of healthcare goods and services may subject us to penalties and adversely impact our reputation, business, results of operations, financial condition, and cash flows.
- Uncertain global and domestic macro-economic and political conditions could materially adversely affect our business, results of operations, and financial condition.
- Our substantial indebtedness could adversely affect our financial condition, our ability to operate our business or react to changes in the economy or our industry, prevent us from fulfilling our obligations under our debts, and divert our cash flow from operations for debt payments.
- The credit agreement that governs the Senior Secured Credit Facilities and the indentures that govern the Senior Notes will each impose significant operating and financial restrictions on our subsidiaries, which may prevent us from capitalizing on business opportunities.
- Medline Inc. is a holding company and its only material assets are its equity interests held directly or indirectly through wholly owned subsidiaries in Medline Holdings, and it is accordingly dependent upon distributions from Medline Holdings to pay taxes, make payments under the tax receivable agreement, and pay any dividends.
- The Designating Stockholders hold a significant percentage of our stock, and their interests may conflict with ours or yours in the future.
- Our amended and restated certificate of incorporation does not limit the ability of our Sponsors, the Mills family, and certain other pre-IPO investors to compete with us, and they may have investments in businesses whose interests conflict with ours.

The market price of shares of our Class A common stock may be volatile or may decline regardless of our operating performance, which could cause the value of your investment to decline.

Market and Industry Data

Unless otherwise indicated, information contained in this Annual Report concerning our industry, competitive position, and the markets in which we operate is based on information from independent industry and research organizations, other third-party sources and management estimates. Although we believe that these third-party sources are reliable, we do not guarantee the accuracy or completeness of this information, and we have not independently verified this information. Management estimates are derived from information obtained from surveys, reports by market research firms, our customers, distributors, suppliers, trade and business organizations, and other contacts in the markets in which we operate and have not been verified by independent sources, and are based on assumptions made by us upon reviewing such data, and our experience in, and knowledge of, such industry and markets, which we believe to be reasonable. In addition, assumptions and estimates of our and our industry's future performance are subject to a high degree of uncertainty and risk due to a variety of factors, including those described in Part I, "Item 1A—Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

Statements regarding our market position (including statements that we are the largest company in a particular market), unless otherwise noted, are based on our 2025 net sales in the relevant market relative to the publicly reported net sales of our competitors in such market, including with respect to our statement of being the largest provider of med-surg products and supply chain solutions serving all points of care, as that statement is based on our 2025 net sales relative to the publicly reported net sales of med-surg products by companies that are both med-surg manufacturers and distributors.

Trademarks

We own or have the right to use trademarks, trade names, and service marks used in connection with our business, including, but not limited to, Medline, Curad, Microtek, Hudson, and Proxima. All trademarks, trade names, and service marks referred to in this Annual Report are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks, or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies. Solely for convenience, our trademarks, trade names, and service marks referred to in this Annual Report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names, and service marks.

PART I

Item 1. Business

General

Medline Inc. (together with its subsidiaries, "Medline", "the Company", "we", "ours" and "us") is the largest provider of medical-surgical ("med-surg") products and supply chain solutions serving all points of care, based on total net sales of med-surg products. Medline was founded in 1966 and today delivers mission-critical products used daily across the full range of care settings, from hospitals and surgery centers to physician offices and post-acute facilities. Our mission is to make healthcare run better by delivering improved clinical, financial, and operational outcomes.

We have two reportable segments, Medline Brand and Supply Chain Solutions, the combination of which addresses critical needs in the market through a comprehensive solution. They are both supported by our Prime Vendor model, differentiated distribution network, and robust commercial platform. Through our two segments, we offer approximately 335,000 med-surg products, including surgical and procedural kits, gloves and protective apparel, urological and incontinence care, wound care, and consumable lab and diagnostics products. We distribute these products through our expansive network of global distribution facilities and our owned fleet of MedTrans trucks.

Medline Brand

As of December 31, 2025, we offer our customers approximately 190,000 med-surg products through our Medline Brand segment and hold leading positions across many key product families for our Medline Brand products. Our Medline Brand products are organized into three product categories: Front Line Care, Surgical Solutions, and Laboratory and Diagnostics.

- *Front Line Care* offers mission-critical med-surg products for patient-facing needs, including wound care products, exam gloves, skin care and incontinence products, environment cleaning supplies, textiles, hand sanitizer, durable medical equipment, patient plastics, and decolonization and infection control products.
- *Surgical Solutions* offers operating room and perioperative environment product solutions, including surgical procedure trays, drapes and gowns, personal protective equipment, sterile wraps, surgical instruments, surgeon's gloves, procedure kits, and orthopedic implants.
- *Laboratory and Diagnostics* offers a full range of laboratory and diagnostic product solutions, including point of care testing, analyzers and instrumentation, lab and diagnostic consumables, diagnostic instruments, vital signs monitors, and anatomic pathology and phlebotomy products.

Our product development approach incorporates customer feedback and ongoing innovation. We are also committed to delivering products of the highest standard, which is reflected by our robust quality team embedded across our manufacturing and sourcing locations. The expertise of our research and development team and quality team helps ensure products bearing the Medline brand meet both our rigorous quality standards and our customers' expectations.

Supply Chain Solutions

As of December 31, 2025, we offer approximately 145,000 med-surg products from over 1,300 third-party suppliers, including nearly all leading national brands, through our Supply Chain Solutions segment. We also provide our customers with supply chain optimization services such as consulting engagements, outsourced warehouse and technology management, put-away-ready packaging, third-party logistics, inventory rationalization, and route planning. Our third-party suppliers are primarily responsible for costs related to import and inbound freight, whereas we are primarily responsible for costs related to outbound freight from our distribution centers. Our supply chain expertise allows us to provide additional service offerings to optimize our customers' supply chain and inventory workflows, helping these customers cost-effectively manage their supply chain while building strong relationships and enhancing retention.

Our Prime Vendor Model

A Prime Vendor relationship is a relationship for which there is a multi-year distribution agreement between Medline and a customer, whereby the customer agrees to use Medline for the vast majority of its med-surg product needs.

In our Prime Vendor relationships, we enter into long-term agreements, typically structured with five-year terms, to act as the primary consolidated logistics partner for these customers' med-surg product needs. These agreements have been and are expected to continue to be a key contributor to our growth. Our customers realize efficiencies by partnering with one supply chain partner to consolidate their med-surg purchase volume. Prior to the market adoption of the Prime Vendor model, customers sourced such products individually from a highly fragmented base of suppliers. The Prime Vendor model instead centralizes procurement and distribution, which in turn drives efficiency and higher service levels.

As Prime Vendor, we drive significant cost savings to our customers. Our scale allows us to deliver consistently lower prices and better service levels on Medline Brand products relative to third-party alternatives, while also lowering the distribution cost for delivery of the full range of med-surg products. This often motivates customers to purchase more Medline Brand products over time. The opportunity is even greater in certain non-acute settings, where we sell a more focused product portfolio. Our Prime Vendor model allows us to provide cost savings to Prime Vendor customers, which, over time, supports incremental purchasing of our Medline Brand products and greater scale across our operations. As our scale grows, we are able to realize further efficiencies by offering superior or similar quality to third-party products at a more cost-effective price. We believe that Medline Brand conversion is mutually beneficial for both our customers and us-the value we provide customers at the outset of a Prime Vendor agreement meaningfully increases over time, as they accrue savings by purchasing our lower cost Medline Brand products, while our profitability grows given the enhanced margin profile of Medline Brand products. This compelling value proposition and supply chain relationship with our customers supports our greater than 98% average Prime Vendor retention rate over the past five years.

A portion of Supply Chain Solutions products sold to existing Prime Vendor customers has like-for-like Medline Brand product equivalents, representing a potential gross profit uplift consistent with our historical margin differentials if such products were converted for Medline Brand products. While we historically have earned higher margins upon conversion from third-party national brand products to like-for-like Medline Brand products, because of the lower average prices for Medline Brand products, there is typically a negative impact on net sales upon the conversion of Supply Chain Solutions products to like-for-like Medline Brand products if volume is assumed to be constant. For additional information on potential risks relating to this conversion opportunity, please see Part I, "Item 1A—Risk Factors—Risks Related to Our Business, Industry and Operations—Our failure to establish and maintain Prime Vendor relationships may cause our revenue to decline."

Our Distribution Network

We have a differentiated distribution network of 70 global distribution centers, warehouses, cross-docks, and transship facilities, 45 of which are in the United States, strategically located to provide next-day delivery to 95% of our U.S. customer base. We utilize artificial intelligence ("AI") and robotics technology in over 26 million square feet of warehouse space in the United States to improve efficiency and capacity to optimize distribution logistics and maximize utilization. The products we distribute are packaged to meet each customer's individual needs and to be "put-away-ready," which streamlines the customer's unloading and shelving process. We also operate our own fleet of more than 2,100 MedTrans trucks that deliver our products across care settings within the United States. As of December 31, 2025, we had approximately 25% in incremental capacity across our platform to support our long-term growth.

Our Commercial Platform

Our deep connectivity to our customers is driven by the strength of our dedicated and tenured commercial team. We have a U.S. commercial team of approximately 4,000 people across all points of care, which includes account managers, product specialists, specialized clinical resources, customer service representatives, supply chain specialists, Prime Vendor analysts, and a robust leadership team dedicated to driving efficiencies for our customers through their teams. We have created an entrepreneurial environment that empowers our salesforce to work with our product managers to create innovative products that meet market demand. We have a team devoted to each channel in the United States and each region or country internationally, which allows our salesforce teams to develop market-specific knowledge.

Research and Development

We have a track record of successfully bringing new products to market, with more than 2,300 granted patents and more than 450 U.S. Food and Drug Administration ("FDA") 510(k) clearances. Over the last three years, we have successfully launched more than 250 new products.

Competition

Our value proposition is derived from our integrated business model, the breadth of our Medline Brand portfolio, our differentiated supply chain, and the overall quality and cost of our products. As a result of our integrated business model, our competitors include both other leading med-surg product manufacturers and distributors.

Similar to us, other leading med-surg product manufacturers produce a wide range of med-surg supplies. However, unlike us, many of these competitors are reliant upon third-party distributors to deliver their products to customers. By nature of being a distributor, Medline has direct access to and manages the end customer relationships. This enables us to offer a complete solution as a manufacturer and a distributor, offering our customers what we believe to be best-in-class supply chain logistics, and driving value through our brand.

Additionally, other distributors of med-surg products similarly connect the fragmented supplier and provider bases and aggregate inventory from suppliers to deliver products to customers, such as McKesson, Cardinal Health, Owens & Minor, and Henry Schein. These distribution companies compete with us for Prime Vendor agreements. However, we believe that many of these competitors do not benefit from the scale and scope of our vertical integration or commercial excellence, and thus are not able to provide the same magnitude of cost savings, value, and holistic solutions that we deliver for our customers.

Production and Raw Materials

We manufacture approximately one-third of our Medline Brand products, which are primarily Class I and II medical devices, through our 30 manufacturing facilities, of which 24 are in North America. We purchase many of the components and raw materials used in manufacturing our products from numerous suppliers. We focus our manufacturing capabilities on products where we can leverage technology and automation to drive higher quality and lower costs to better serve our customers. For the vast majority of the other two-thirds of our Medline Brand products, we work closely with our network of more than 600 global partners across approximately 40 countries, many of whom have decades-long exclusive relationships with us. The breadth of our global sourcing partnerships provides diversification and strengthens our resiliency, with no single sourcing partner accounting for more than 5% of total spend as of December 31, 2025.

We also have plans and measures in place to help ensure continuity of supply while maintaining high quality and reliability. Generally, we have been able to obtain adequate supplies of such raw materials and components. However, due to the FDA's manufacturing requirements and those of other regulatory authorities, we may not be able to quickly establish additional or replacement sources for certain components, materials or processes if we experience a sudden or unexpected reduction or interruption in supply or services and are unable to develop alternative sources.

Human Capital Resources

At Medline, our relentless focus on the customer drives our human capital strategy, which revolves around attracting, developing, and retaining employees to provide the best products and services for our customers. We have developed a strong foundation that drives our recruitment, retention and development efforts. We are committed to supporting the personal and professional development of our employees, as well as providing competitive benefits and a safe, inclusive workplace.

As of December 31, 2025, we employed over 45,000 employees worldwide, with over 26,000 located in the United States. Our largest non-U.S. employee populations are in Mexico, Dominican Republic, India, Canada, Slovakia, France, China, Japan, Germany, and Australia. None of our employees in the United States are unionized, though some of our employees in Mexico belong to unions. In Germany and the Netherlands, employees are represented through Works Councils; in France and Spain, employees are represented through both Works Councils and industry-wide collective bargaining agreements; and in Belgium and Italy, employees are also represented through industry-wide collective bargaining agreements. In Australia, certain employees are represented by an enterprise bargaining agreement; in Japan, employees are represented through a Work Council; and in Vietnam, employees are represented through a collective bargaining agreement. We believe that our positive employee relations and total employee experience drive the continual growth of our workforce.

Culture and Values

Our culture is grounded in a customer-focused, collaborative, and performance-driven approach, guided by core values emphasizing relentless customer focus, agility and flexibility, problem-solving, drive to succeed, purposeful candor, and the importance of relationships. Employees are encouraged to exercise judgment, work transparently with customers, and contribute meaningfully to our mission to make healthcare run better.

Talent Attraction and Development

We seek to attract employees whose skills, experience, and motivation align with our operational and technical needs. Through continual improvement of internal processes, an awareness of market and candidate driven trends, and in partnership with vendors and other outside organizations, our talent acquisition programs focus on efficient hiring processes, market awareness, and building a diverse pipeline of candidates. We support development through consistent performance management processes and early career opportunities to take on additional responsibilities to demonstrate their competencies and drive to succeed and on-the-job responsibility augmented by formal training and development to refine technical and leadership skills. New sales representatives participate in comprehensive training programs, and product managers have targeted development pathways through all stages of their careers, from mandatory onboarding offerings to advanced classes that provide the necessary skills with increasing levels of responsibility, to support progression over time.

Employee Engagement and Inclusion

We believe our employees' ability to communicate and cooperate effectively across functional and departmental teams positively impacts our performance. We engage in various listening strategies and foster engagement through survey feedback mechanisms, anonymous employee feedback platform, focus groups, increased attention to onboarding and offboarding feedback, pulse surveys on remote work needs, and other listening strategies. Insights from these efforts inform workplace improvements. We also support an inclusive environment through Employee Resource Groups and leadership training initiatives designed to reduce bias in talent decisions and strengthen representation across the company.

Health, Safety, and Well-Being

We are committed to maintaining a safe workplace and supporting the physical, emotional, and financial well-being of our employees. We provide competitive health and benefits programs, access to assistance resources where available, and opportunities for community involvement through charitable giving, including financial giving and in-kind giving such as product donations.

Intellectual Property

We rely upon patents, trademarks, copyrights, trade secrets and other intellectual property rights to maintain and improve our competitive position. We have a large portfolio of intellectual property, including more than 2,300 granted patents as well as trademark registrations protecting our notable brands, including Medline, Curad, Microtek, Hudson, and Proxima.

We consider the trademarks and know-how that we own to be material to our business. However, other than the Medline mark, we do not consider our business to be materially dependent upon any individual trademark registration or trade secret. In the aggregate, we consider our more than 2,300 granted patents to be material to our business. However, no single patent or group of related patents is material to our business as a whole or any segment of our business.

We believe that we have taken all necessary steps to protect our intellectual property rights, but no assurance can be given that we will be able to successfully enforce or protect our rights in the event that they are infringed upon or challenged by a third party. See Part I, "Item 1A —Risk Factors—Risks Related to Regulation and Legal Proceedings—Any failure to obtain, maintain, protect and enforce our intellectual property rights, or the failure of the strength or scope of our intellectual property rights, could harm our business, financial condition, and results of operations" and "—Risks Related to Regulation and Legal Proceedings—We may become subject to litigation brought by third parties claiming infringement, misappropriation, or other violation by us of their intellectual property rights."

Government Regulation

Our operations and products are subject to extensive regulation by numerous governmental regulatory authorities, including U.S. and other international regulatory authorities, and other government agencies inside and outside the United States. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, design, materials, testing, safety, efficacy, quality, purity, manufacturing, methods, controls, testing, screening, recordkeeping, reporting, processing, storage, registration, authorization, licensing, permitting, labeling, advertising, marketing, distribution, offer for sale, sale, use, expiration, pricing, reimbursement, import, export, clinical trials, post-marketing surveillance of our products, the registration of our facilities, and the claims that we make about our products. The United States and other countries where we sell healthcare and other regulated products, including drugs, human cell and tissue products, dietary supplements, cosmetics, certain foods, and consumer products subject such products to their own clearance, authorization, approval, registration, listing, labeling, manufacturing, recordkeeping, reporting, and other regulatory requirements regarding the performance, safety, and quality of such products. We are also subject to healthcare and other regulations and enforcement by the federal government and the states and foreign governments and authorities in the locations in which we conduct our business. The U.S. governmental and regulatory authorities that enforce such laws and rules, and that issue guidance on compliance with such laws and rules include, without limitation, the FDA, the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the U.S. Department of Health and Human Services ("HHS"), the HHS Office of Inspector General, U.S. Environmental Protection Agency ("EPA"), the Federal Trade Commission ("the FTC"), Consumer Product Safety Commission ("CPSC"), the U.S. Department of Justice ("DOJ") and individual U.S. Attorney offices within the DOJ, as well as state and local governments. Our business is also affected by patient and data privacy and security laws, government payer cost containment initiatives, government reimbursement laws and regulations, environmental, health, and safety laws and regulations, as well as laws and regulations with respect to the sale, transportation, storage, handling, and disposal of hazardous or potentially hazardous substances, and safe working conditions. Our business also maintains contracts with governmental agencies and such contracts are subject to various government procurement laws and regulations, required contract provisions, and other requirements relating to contract formation, administration and performance. Failure to comply with applicable laws and regulations or with contractual or other requirements may result in monetary damages and criminal or civil penalties as well as termination of our government contracts or our suspension or debarment from government contract work.

The regulations to which we are subject are complex and have tended to become more stringent over time. If our business expands in certain ways, including through the offering of new products and services or entering into new geographic areas, we may be subject to new and additional regulatory requirements. The foreign, federal, state, and local regulatory authorities have broad inspection and enforcement powers, including the ability to suspend or limit the distribution of products, suspend, revoke, or terminate our product and facility licenses, permits, and authorizations, request the cessation of distribution and shipments of certain products due to regulatory, safety, or other issues, seize or order the recall of our products, issue safety, quality, or other communications to the public or healthcare providers, enforce laws related to marketing, including promotion of off-label uses of products, and impose injunctions and significant criminal, civil, and administrative sanctions for violations of laws and regulations. Any adverse regulatory or other action, including any adverse press releases or other communications from regulators, may impact our business practices and operations, including by limiting our ability to effectively market, ship, and sell our products, affecting the production and distribution of products by our manufacturing facilities, subjecting us to significant liability, and limiting our ability to obtain future authorizations. Although we are subject to international government regulations in the international end markets where we operate and/or provide our products, these regulations do not have a material impact on our products as no international market represents more than 3% of our net sales.

Government Regulation of Medical Devices

Our medical devices are subject to regulation by numerous government agencies, including the FDA and comparable state and foreign agencies. Regulations of the FDA and other regulatory agencies in and outside the United States impose extensive compliance and monitoring obligations on portions of our business. The FDA and other U.S. and foreign governmental agencies regulate, among other things, with respect to medical devices: design, development, and manufacturing; testing, registration, listing, labeling, content, and language of instructions for use and storage; clinical trials; product safety; marketing, sales, and distribution; licensing and permit requirements; premarket clearance, approval and authorization; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval studies; and product import and export. The regulations to which we are subject are complex and have tended to become more stringent over time. If our business expands in certain ways, we may be subject to new and additional regulatory requirements. The FDA and state regulatory authorities have broad inspection and enforcement powers, including the ability to suspend or limit the distribution of products by our distribution centers; seize or order the recall of products; terminate, suspend, or revoke licenses and permits; and impose significant criminal, civil, and administrative sanctions for violations of these laws and regulations. Foreign regulations subject us to similar foreign enforcement powers. In addition, the FDA and other governmental and regulatory authorities, both in and outside the United States (including the FTC, the HHS Office of the Inspector General, the DOJ, and various state Attorneys General), monitor the promotion and advertising of our products. Any adverse regulatory or other action, including any adverse press releases or other communications from regulators, depending on its magnitude, may limit our ability to effectively market, ship, and sell our products, limit our ability to obtain future premarket authorizations, or result in a substantial modification to our business practices and operations.

FDA Premarket Clearance and Approval Requirements

Each medical device we wish to distribute commercially in the United States requires marketing authorization from the FDA prior to distribution, unless the device is exempt from premarket notification requirements. The type of marketing authorization necessary is generally linked to the classification of the device. The FDA classifies medical devices into one of three classes-Class I, II, or III-based on the degree of risk associated with a device and the level of regulatory control deemed necessary to ensure its safety and effectiveness. Class I devices that pose the least risk are subject only to General Controls applicable to all devices, such as requirements for device labeling, premarket notification, and adherence to current good manufacturing practices for devices as set forth in the Quality System Regulation ("QSR"). Class II devices that pose a moderate risk are subject to General Controls and may also be subject to Special Controls, such as performance standards, product-specific guidance documents, special labeling requirements, patient registries, or post-market surveillance. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through General and Special Controls, including devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential unreasonable risk of illness or injury.

Most Class I devices and some Class II devices are exempted by regulation from the 510(k) clearance requirement and can be marketed without prior authorization from the FDA. Class I and II devices that are not exempted are eligible for marketing through the 510(k) clearance pathway. By contrast, devices placed in Class III generally require premarket approval ("PMA") or de novo clearance prior to commercial marketing. The PMA approval process is more stringent, time-consuming and expensive than the 510(k) clearance process; however, the 510(k) clearance process has also become increasingly stringent and expensive. None of our products are currently approved under a PMA, and we have no plans for any indication or system improvement or extension that we believe would require a PMA. If, in the future, we were to file a PMA, we may be subject to additional regulatory requirements.

510(k) Clearance Process

To obtain 510(k) clearance, we must submit a premarket notification to the FDA demonstrating the proposed device to be substantially equivalent to a predicate device. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and it has either the same technological characteristics, or it has different technological characteristics, but the information provided in the 510(k) submission demonstrates that the device does not raise new questions of safety or effectiveness. The standard review process for 510(k)s is between six to nine months, dependent upon the type of 510(k) filing submitted. Although many 510(k) premarket notifications are cleared without clinical data, in some cases, the FDA may require clinical data to support substantial equivalence. In reviewing a premarket notification, the FDA may request additional information, including clinical data, which may significantly prolong the review process and clearance is never assured. Clinical trials generally require the submission of an investigational device exemption ("IDE") to the FDA for a specified number of patients and study sites, unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements. Clinical trials are subject to numerous requirements and institutional review board approval, oversight, and monitoring. Even if a trial is conducted, the results of clinical testing may not adequately demonstrate the safety and effectiveness of the device or be sufficient to obtain FDA clearance or approval for marketing.

After a device receives 510(k) clearance, any subsequent modification of the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require submission and approval of a de novo 510(k) or a PMA application in cases where new indications are sought for which there is no predicate. Non-significant changes are handled via internal documentation by the Company. Each manufacturer must judge the significance of modifications based on FDA 510(k) regulatory requirements and guidance documents. The FDA may review any such decision and may disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA may require the manufacturer to cease marketing and distribution and/or recall the modified device until 510(k) clearance or PMA approval is obtained. In the future, we may make modifications to our products after they have received FDA clearance and, in appropriate circumstances, determine that new clearance is unnecessary. However, the FDA may disagree with our determination, and, if the FDA requires us to seek 510(k) clearance or submit new PMA applications for any modifications to a previously cleared product, we may be required to cease marketing or distributing or recall the modified device until we obtain the required clearance or approval. We may also market or acquire products that are marketed without a 510(k) clearance, appropriate labeling, or that otherwise are marketed in violation of FDA requirements, since medical devices can be marketed only for the indications for which they are cleared or approved. Under these circumstances, we may also be subject to warning letters, significant regulatory fines, or other penalties, and we may no longer be able to market particular products for which a 510(k) clearance is required.

Post-Marketing Requirements

Numerous FDA regulatory requirements apply to devices we manufacture and distribute, including: compliance with the QSR, which require manufacturers and their suppliers to follow the applicable design, testing, processes, control, documentation, labeling, and other quality assurance procedures during the manufacturing process; establishment registration, which requires establishments involved in the production and distribution of medical devices intended for commercial distribution in the United States to register with the FDA; medical device listing, which requires manufacturers to list the devices they have in commercial distribution with the FDA; labeling regulations, which prohibit "misbranded" devices from entering the market, as well as prohibit the promotion of products for unapproved or off-label uses and impose other restrictions on labeling; post-market surveillance, including medical device reporting requirements which requires manufacturers to report to the FDA if their device may have caused or contributed to a death or serious injury, or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act that may present a risk to health. The FDA and other governmental and regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

The FDA enforces these requirements by inspection and market surveillance. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA may also inspect foreign facilities that export products to the United States. Failure to comply with applicable regulatory requirements may result in enforcement action or other actions by the FDA, which may include one or more of the following sanctions: adverse press releases and safety communications; requests to stop shipments; untitled letters or warning letters; fines, injunctions, and civil penalties; mandatory recall or seizure of our products; customer notifications and repairs or replacements; administrative detention or banning of our products; consent decrees; operating restrictions, partial suspension or total shutdown of production; refusing our request for 510(k) clearances for new product versions or modifications to existing product versions; revocation of 510(k) clearances previously granted; refusal to grant export approval for our products; and criminal prosecution and penalties. If any of these events were to occur, they could have a material adverse effect on our business, financial condition, and results of operations.

International Regulation of Medical Devices

Sales of medical devices outside the United States are subject to foreign government regulations, which vary substantially from country to country. In order to market our products in other countries, we must comply with applicable regulatory requirements and authorizations and approvals and safety and quality regulations in each country in which the product is marketed. The time required to obtain authorization, approval, or certification by a foreign country may be longer or shorter than that required for FDA clearance, and the requirements may differ significantly.

EU Regulation of Medical Devices

In the European Union ("EU") until May 25, 2021, medical devices were regulated by the Council Directive 93/42/EEC, which has been repealed and replaced by the Medical Device Regulation ("EU MDR"). Unlike directives, regulations are directly applicable in all EU member states without the need for member states to implement into national law. The EU extended the EU MDR transitional periods for certain medical devices until December 31, 2027 or December 31, 2028, depending on a device's risk class and subject to certain conditions to ensure continued access to medical devices for patients and to allow medical devices already placed on the market in accordance with the current legal framework to remain on the market, provided that the requirements of the transitional provisions are fulfilled.

In the EU, there is currently no premarket government review of medical devices. However, all medical devices placed on the EU market must meet general safety and performance requirements, and compliance with the general safety and performance requirements is a prerequisite for European conformity marking without which medical devices cannot be marketed or sold in the EU. EU MDR requirements regarding the distribution, marketing, and sale, including quality systems and post-market surveillance, have to be observed by manufacturers, importers, and distributors as of the application date (i.e., since May 26, 2021), including registration of economic operators and of devices (once the relevant modules of Eudamed are functional), surveillance, and vigilance requirements. The aforementioned EU rules are generally applicable in the European Economic Area which consists of the 27 EU member states plus Norway, Liechtenstein, and Iceland.

The NDA Approval Process

For any new drug products regulated under the Federal Food, Drug, and Cosmetic Act such as our ReadyPrep CHG cloth, a sponsor must submit a New Drug Application ("NDA"), to the FDA for review and approval. The NDA review and approval process may take multiple years and involves steps including the following:

- completion of preclinical studies and analytical and stability testing in accordance with applicable regulations;
- submission to the FDA of an Investigational New Drug ("IND") application, which must become effective before clinical trials may begin and must be updated annually and amended when certain changes are made;
- approval by an institutional review board, or IRB, or independent ethics committee, or IEC, at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements, including informed consent, financial disclosure by investigators, and other clinical trial-related regulations, to establish the safety and efficacy of the investigational product for each proposed indication and other condition of use;
- preparation and submission to the FDA of an NDA;

- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance;
- satisfactory completion of FDA inspection of select clinical trial sites involved in conducting pivotal studies that generated the data in support of the NDA;
- payment of user fees for FDA review of the NDA; and
- FDA review and approval of the NDA, including of the proposed prescribing information and, where applicable, consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States.

Any approvals that we may ultimately receive could be withdrawn if required post-marketing trials or analyses do not meet the FDA requirements, which could materially harm the commercial prospects for our products.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution, or post-marketing study requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delay in obtaining, or failure to obtain, regulatory approval for our candidate products, or obtaining approval but for significantly limited use, would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Trade Regulations

The movement of products, services, and investment across borders subjects us to extensive trade regulations. A variety of laws and regulations in the countries in which we transact business apply to the sale, shipment, and provision of goods, services, and technology across borders. These laws and regulations govern, among other things, our import, export, and other business activities. We are also subject to the risk that these laws and regulations could change in a way that would expose us to additional costs, penalties, or liabilities. Some governments also impose economic sanctions against certain countries, governments, persons, and entities, both for unlawful or malign conduct and to discourage or prevent entities from abiding by other countries' laws. In addition to our need to comply with such regulations in connection with our direct activities, we also sell and provide goods, technology, and services to agents, representatives, and distributors who may export such items to customers and end-users. If we, or the third parties through which we do business, are not in compliance with applicable import, export control, or economic sanctions laws and regulations, we may be subject to civil or criminal enforcement action and varying degrees of liability. Such actions may disrupt or delay sales of our products or services or result in restrictions on our distribution and sales of products or services that may materially impact our business.

Anti-Boycott Laws

Under U.S. laws and regulations, U.S. companies and their subsidiaries and affiliates are prohibited from participating or agreeing to participate in unsanctioned foreign boycotts in connection with certain business activities, including the sale, purchase, transfer, shipping, or financing of goods or services within the United States or between the United States and countries outside of the United States. If we, or certain third parties through which we sell or provide goods or services, violate U.S. anti-boycott laws and regulations, we may be subject to civil or criminal enforcement action and varying degrees of liability.

Data Privacy and Security Laws and Regulations

Our business includes the processing of personally identifiable information ("Personal Data") of consumers; Medline applicants, employees, and other workforce members; our customers' patients, plan members, and employees; our vendors' employees; and other third parties, as well as protected health information ("PHI"), where we continue to meet the definition of a Business Associate on behalf of our customers for certain parts of our business. We maintain PHI that we Processed about Medline's own patients under certain of our historic offerings. We are directly or, through our customers, indirectly subject to numerous and evolving federal, state, and foreign laws and regulations relating to the processing of Personal Data and PHI, such as the Health Insurance Portability and Accountability Act of 1996, as amended, and the regulations that implement the law and its amendments (collectively, "HIPAA"), the Telephone Consumer Protection Act of 1991 ("TCPA"), the Payment Card Industry Data Security Standard, Section 5 of the Federal Trade Commission Act (the "FTCA"), and the EU's General Data Protection Regulation and its UK equivalent ("UK GDPR" and collectively, "GDPR"), the California Consumer Privacy Act, which was further expanded by the California Privacy Rights Act of 2020 ("CPRA" and collectively, "CCPA"), and similar data privacy legislation enacted or under consideration by various other U.S. states, and U.S. state data breach notification laws.

HIPAA establishes privacy and security standards that limit our use and disclosure of PHI and requires us to implement administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and availability of PHI, as well as to notify affected individuals, the HHS Office for Civil Rights ("OCR"), and, in breaches involving 500 individuals or more in a state / jurisdiction, the media, of breaches of unsecured PHI when we are acting as a Covered Entity. If we are acting as a Business Associate, we must notify our Covered Entity clients of breaches of unsecured PHI and security incidents. HIPAA contains substantial restrictions and requirements with respect to the use and disclosure of certain PHI. These restrictions and requirements are subject to change. For example, in December 2024, OCR issued a notice of proposed rulemaking to update the HIPAA security rule with respect to the cybersecurity of electronic PHI. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. In addition, OCR performs compliance audits in order to proactively enforce the HIPAA privacy and security standards. OCR has the discretion to impose penalties and may require companies to enter into resolution agreements and corrective action plans which impose ongoing compliance requirements. OCR enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition to enforcement by OCR, state Attorneys General are authorized to bring civil actions under either HIPAA or relevant state laws seeking either injunctions or damages in response to violations that threaten the privacy of state residents.

In addition to HIPAA, we must adhere to U.S. state patient privacy laws that are not pre-empted by HIPAA, including those that are more stringent than HIPAA requirements. Numerous other U.S. state, federal, and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality, and security of patient health information. In addition, Congress and some U.S. states are considering new laws and regulations that further protect the privacy and security of medical records or medical information. With the recent increase in publicity regarding data breaches resulting in improper dissemination of consumer information, all states have passed laws regulating the actions that a business must take if it experiences a data breach, such as prompt disclosure to affected customers. The FTC and states' Attorneys General have also brought enforcement actions and prosecuted some data breach cases as unfair and/or deceptive acts or practices under the FTC Act, in addition to actions related to the Health Breach Notification Rule ("HBNR").

In the United States, the FTC is increasingly active in regulating health-related privacy and security, including by holding companies accountable for statements or promises made about the privacy or security of health information, through Section 5 of the FTCA, which prohibits unfair or deceptive acts or practices. In addition, the FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. For information that is not subject to HIPAA and deemed to be "personal health records," the FTC may also impose penalties for violations of the HBNR to the extent we are considered a "personal health record-related entity" or "third party service provider." As a result, we may be subject to scrutiny by federal and state regulators, partners, and consumers related to our collection, use, and disclosure of consumer Personal Data, including health information. Additionally, federal and state consumer protection laws continue to be applied by FTC and states' Attorneys General to regulate the collection, use, storage, and disclosure of Personal Data.

At the state level in the United States, the CCPA added new privacy protections for California residents with respect to certain types of Personal Data, including by introducing new data privacy rights for California residents and establishing a regulatory agency dedicated to enforcing compliance. The CPRA came into effect on January 1, 2023, applying to information collected by businesses on or after January 1, 2022. Various other U.S. states have enacted similar comprehensive consumer data privacy legislation, and several other U.S. states and countries are considering expanding or passing privacy laws in the near term. Further, states such as Washington, Connecticut, and Nevada have recently enacted broadly applicable laws to protect the privacy of personal health information, which generally require regulated entities to obtain consent for the collection, use, or sharing of any "consumer health data," which may include Personal Data that is linked or reasonably linkable to a consumer and that identifies a consumer's past, present, or future physical or mental health. The effects of such state privacy laws are potentially far-reaching and may require us to modify our data Processing practices and policies and incur substantial compliance-related costs and expenses, and it remains unclear how various provisions will be interpreted and enforced by the courts and regulators. It remains possible that the U.S. Congress will ultimately (despite many failed attempts over the past several years) enact a comprehensive federal privacy law that would preempt or partially preempt U.S. state comprehensive privacy laws, but it also remains a possibility that a federal U.S. comprehensive privacy law would not preempt state law but instead layer on additional compliance complexity.

Similarly, many foreign laws and regulations, including in countries in which we currently operate, govern the Processing of Personal Data. For example, the GDPR imposes requirements for controllers and processors subject to the law with respect to Processing the Personal Data of EU and UK residents. Guidance on implementation and compliance practices is often updated or otherwise revised. Ensuring compliance with the GDPR is an ongoing commitment that involves substantial costs, and despite our efforts, data protection authorities or others (including individual consumers) may assert that our business practices fail to comply with its requirements. If our operations are found to violate GDPR requirements, we may incur substantial fines and other penalties, required changes to our business practices and reputational harm, any of which could have an adverse effect on our business. Such penalties are in addition to any civil litigation claims by data controllers and data subjects. Laws and regulations relating to privacy and data protection are continually evolving and subject to potentially differing interpretations by various courts and regulators. The effects of the new privacy laws are potentially far-reaching and may require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses, and it remains unclear how various provisions will be interpreted and enforced by the courts and regulators.

In addition to our product offerings, we also provide electronic medical devices and other digital tools which can connect to each other and to other technology. Many of the laws referenced above also contain requirements to have appropriate technical and organizational security controls and measures in place for such technologies and technical infrastructure. We must manage the information security as well as privacy risks of these connected systems to ensure secure and effective exchange and use of exchanged information. Perceived or actual security vulnerabilities in our products or services, or the perceived or actual failure by us or our customers who use our products or services to comply with applicable legal or contractual data privacy and security requirements, may not only cause us significant reputational harm, but may also lead to claims against us by our customers and/or governmental and regulatory authorities and involve substantial fines, penalties and other liabilities and expenses, and costs for remediation.

In the event of a privacy or security incident or claim that we, a service provider, or a third party with which we do business has violated applicable privacy or security laws and regulations, we may be subject to regulatory or legal action. If legislation or regulations are changed or expanded, or if governing jurisdictions interpret or implement legislation or regulations in new ways, it could require changes in our business practices and adversely affect our business, financial condition, and results of operations.

Healthcare Fraud and Abuse Laws and Regulations

Certain of our businesses involve the marketing and sale of, and third-party payment for, med-surg products that are subject to extensive state, federal, and foreign governmental laws and regulations. U.S. laws and regulations are imposed primarily in connection with government healthcare programs, such as the Medicare, Medicaid, and TRICARE programs, as well as the government's interest in regulating the quality and cost of healthcare. U.S. federal healthcare laws apply when we or our customers submit claims for items or services that are reimbursed under government healthcare programs, including laws related to kickbacks, false claims, self-referrals and healthcare fraud. We have been, and may in the future be, subject to CMS audits of our performance to determine our historical compliance with CMS contracts and regulations. Other governments also impose laws and regulations in connection with their healthcare reimbursement programs and the delivery of healthcare items and services.

Our med-surg products are purchased principally by hospitals and physicians that typically bill various third-party payers, including government healthcare programs, private insurance plans and managed care plans, for the healthcare services provided to their patients. We also directly submitted claims to government healthcare programs as a Medicare-enrolled durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS") supplier. As a result, we have been and from time to time are subject to audits by government healthcare programs and third-party payers related to such claims, which may require actions including refunds of overpayments and may result in penalties, litigation or enforcement actions. Although we divested the assets associated with this DMEPOS supplier business unit in October 2023, we may nonetheless be subject to past and future product liability claims, enforcement actions, regulatory investigations, fines and penalties, regardless of their ultimate outcome, any of which could harm our reputation and have a material adverse effect on our business, results of operations and financial condition.

Key federal fraud and abuse laws include the federal Anti-Kickback Statute (the "AKS"), the Stark Law, False Claims Act (the "FCA"), and the Civil Monetary Penalties Law (the "CMP Law"). The AKS prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, or receiving any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, to induce, reward, or in return for the referral of an individual for, or the purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item, or service reimbursable, in whole or in part, by Medicare, Medicaid, or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including cash, improper discounts, and free or reduced price items and services. Among other things, the AKS has been interpreted to apply to arrangements between pharmaceutical, biotechnology, and medical device manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not meet the requirements of a statutory or regulatory exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare program-covered business, the AKS has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil monetary penalties of up to $124,732 (which is adjusted annually for inflation) for each violation, plus up to three times the remuneration involved, and may result in criminal fines and imprisonment of up to ten years, and/or exclusion from Medicare, Medicaid, or other governmental programs.

Federal law also includes a provision commonly known as the Stark Law, which prohibits a physician from referring Medicare or Medicaid patients to an entity providing "designated health services," which includes DME, if the physician or immediate family member of the physician has an ownership or investment interest or compensation arrangement with such entity that does not comply with the requirements of a Stark exception. Violation of the Stark Law could result in denial of payment, disgorgement of reimbursements received under a non-compliant arrangement, civil penalties, and exclusion from Medicare, Medicaid, or other governmental programs.

The federal false claims and civil monetary penalties laws, including the civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to or approval by the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Further, a claim including items or services resulting from a violation of the federal AKS or Stark Law also constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the U.S. government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act and the accompanying threat of significant liability in its investigation and prosecution of pharmaceutical, biotechnology, and medical device companies throughout the country. Manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims, for example, in connection with the promotion of products for unapproved or off-label uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from $13,946 to $27,894 (which are adjusted annually for inflation) for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid, TRICARE, and other federal healthcare programs. In addition, companies found liable under the False Claims Act have been forced to implement extensive corrective action plans and have often become subject to consent decrees or corporate integrity agreements, severely restricting the manner in which they conduct their business and imposing ongoing reporting and disclosure obligations.

The federal CMP Law imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The fraud and abuse laws and regulations have been subject to heightened enforcement activity over the past few years, and significant enforcement activity has been the result of qui tam "relators" who serve as whistleblowers by filing complaints in the name of the United States (and, if applicable, particular states) under applicable false claims laws, and who may receive up to 30% of total government recoveries. Penalties under fraud and abuse laws may be severe and could result in significant civil and criminal penalties and costs, including the loss of licenses and the ability to participate in federal and state healthcare programs. Such penalties could have a material adverse effect on our business, results of operations and financial condition. Also, these measures may be interpreted or applied by a prosecutorial, regulatory, or judicial authority in a manner that could require us to make changes in our operations or incur substantial defense and settlement expenses. Given the significant size of actual and potential settlements, it is expected that governmental authorities will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws. Even unsuccessful challenges by regulatory authorities or private relators could result in reputational harm and the incurring of substantial costs.

In addition, as a manufacturer of FDA-cleared devices reimbursable by federal healthcare programs, we are subject to the Physician Payments Sunshine Act (the "Sunshine Act"), which requires us to annually report certain payments and other transfers of value we make to U.S.-licensed physicians, as defined by statute, certain other healthcare professionals and U.S. teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The Sunshine Act pre-empts similar state reporting laws, although we or our subsidiaries may be required to report under certain state transparency laws that address circumstances not covered by the Sunshine Act, and some of these state laws, as well as the federal law, can be ambiguous.

Most states have adopted similar laws related to transparency, kickbacks, false claims, and self-referrals that apply to products or services covered by state Medicaid and other healthcare programs and private third-party payers, some of which apply to manufacturers and suppliers of items reimbursed by any payor, including commercial payors. In addition, these state laws have their own penalties, which may be in addition to federal penalties.

We are also subject to foreign regulations requiring transparency of certain interactions between suppliers and their customers. Many member states in the EU have adopted specific anti-gift statutes that further limit commercial practices for medical devices, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities. In addition, many EU member states have adopted such national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs. Any failure to comply with these laws and regulations could subject us or our officers and employees to criminal and civil financial penalties.

While we believe that we are substantially compliant with applicable fraud and abuse laws and regulations, and have implemented compliance programs and controls in place designed to ensure substantial compliance, we cannot predict whether changes in applicable law, or interpretation of laws, or changes in our services or marketing practices in response to changes in applicable law or interpretation of laws, or failure to comply with applicable law, could have a material adverse effect on our business, results of operations and financial condition.

Implementation of legislative or regulatory reforms to reimbursement systems, or adverse decisions relating to our products by administrators of these systems in coverage or reimbursement, could significantly reduce reimbursement or result in the denial of coverage, which could have an impact on the acceptance of and demand for our products and the prices that our customers are willing to pay for them.

Environmental, Health and Safety Requirements

We are subject to various environmental, health and safety ("EHS") requirements both inside and outside the United States. Like other companies in our industry, our manufacturing and other operations involve air emissions, wastewater and stormwater discharges, and the storage, use, and management of hazardous and other sensitive materials, and the disposal of hazardous waste. We are also subject to requirements relating to safe working conditions and laboratory practices. Our operations involve the use of substances regulated under EHS requirements, primarily in our manufacturing and sterilization processes. We believe we have implemented policies, practices and procedures that enable us to comply with applicable EHS requirements. However, EHS requirements may be detailed and complex, and we sometimes have been cited for violations of such requirements and may be cited for violations in the future. In addition, many such requirements are becoming increasingly stringent, and we are sometimes required to make changes to our operations for continued compliance, which can require substantial capital investments as well as increases in operating costs. See Part I. "Item 1A—Risk Factors—Risks Related to Regulation and Legal Proceedings—We are subject to extensive environmental, health and safety requirements, and our operations involve hazardous and other environmentally sensitive substances."

For example, we, as well as others in our industry, rely on ethylene oxide ("EtO") to sterilize certain medical products that we manufacture. In light of evolving science regarding risks related to EtO exposure, regulatory actions have been taken by some jurisdictions to reduce EtO emissions, and we have made substantial improvements to our two primary EtO sterilization facilities to meet such requirements and otherwise manage EtO emissions. There also has been a significant increase in regulations regarding per- and polyfluoroalkyl substances ("PFAS") in both the United States and Europe, including new and evolving regulations that prohibit the use (or require disclosure of the presence) of certain forms of PFAS in products. PFAS are ubiquitous in manufacturing, and not all forms of PFAS have been found to be hazardous to human health. We are actively developing and implementing protocols to comply with evolving regulations.

Operating, Security and Licensure Standards

We are subject to certain operational, security, and licensure requirements, including the federal Drug Supply Chain Security Act ("DSCSA") in the United States, which mandates an industry-wide, national serialization system for pharmaceutical packaging with a ten-year phase-in process. By November 2018, all manufacturers and re-packagers were required to mark each prescription drug package with a unique serialized code. The DSCSA also establishes certain requirements for the licensing and operation of prescription drug wholesalers and third-party logistics providers and includes the eventual creation of national wholesaler and third-party logistics provider licenses in cases where states do not license such entities. In addition, with respect to our durable medical equipment ("DME") business, we are subject to certain state licensure laws (including state pharmacy laws), and also certain accreditation standards, including to qualify for reimbursement from Medicare and other third-party payers.

We are also subject to the FDA's unique device identification system requirements, which require "labelers" to include unique device identifiers ("UDIs"), with a content and format prescribed by the FDA and issued under a system operated by an FDA-accredited issuing agency, on the labels and packages of medical devices and to directly mark certain devices with UDIs. The UDI regulations also require labelers to submit certain information concerning UDI-labeled devices to the FDA.

Certain of our businesses are also required to register for permits and/or licenses with various state boards of pharmacy, state health departments and/or comparable state agencies as well as comparable foreign agencies, and certain accrediting bodies, depending on the type of operations and location of product distribution, manufacturing or sale. These businesses include those that distribute, manufacture, and/or repackage medical products, or own pharmacy operations.

Antitrust and Consumer Protection

The federal government of the United States, most U.S. states, and many foreign countries have antitrust laws that prohibit certain types of conduct deemed to be anti-competitive, as well as consumer protection laws that seek to protect consumers from improper business practices. At the U.S. federal level, the FTC, CPSC and DOJ oversee enforcement of these types of laws, and states have similar government agencies. Violations of antitrust or consumer protection laws may result in various sanctions, including criminal and civil penalties. Private plaintiffs may also bring civil lawsuits against us in the United States for alleged antitrust law violations, including claims for treble damages. EU law also regulates competition and provides for detailed rules protecting consumers.

International Transactions

U.S. and foreign import and export laws and regulations require us to abide by certain standards relating to the importation and exportation of products, including but not limited to the absence of forced labor in our supply chain. We also are subject to certain laws and regulations concerning the conduct of our foreign operations, including the U.S. Foreign Corrupt Practices Act (the "FCPA"), U.S. export control laws, the UK Bribery Act, German anti-corruption laws, and other anti-bribery laws and laws pertaining to the accuracy of our internal books and records, as well as other types of foreign requirements similar to those imposed in the United States.

While we believe that we are substantially compliant with the foregoing laws and regulations promulgated thereunder and possess all material permits and licenses required for the conduct of our business, and while we have policies against and seek to avoid the import of goods that are manufactured in whole or in part by forced labor or other exploitative labor practices, there can be no assurance that regulations that impact our business or customers' practices will not have a material adverse effect on our business, results of operations and financial condition.

Corporate Information

We were incorporated in Delaware in November 2024 under the name of Medline Inc. Our principal executive offices are located at 3 Lakes Drive, Northfield, Illinois 60093. Our telephone number is (847) 949-5500. Our website address is www.medline.com. Information contained on, or that can be accessible through, our website is not a part of this Annual Report.

Available Information

We file electronically with the SEC our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements and other forms or reports as required. Our filings with the U.S. Securities and Exchange Commission (the "SEC") are available to the public over the Internet at the SEC's website at www.sec.gov. We also use our investor relations website at ir.medline.com, press releases, public conference calls and webcasts, and social media as routine channels of distribution to communicate important, and often material, information about Medline to investors and the public, including information about our financial performance and results, analyst and investor presentations, investor days, products, solutions, sustainability initiatives, and corporate governance practices. We encourage you to follow these channels, in addition to our SEC filings, for timely information about the Company. Our SEC filings, including Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), are available free of charge on our investor relations website as soon as reasonably practicable after they are filed with or furnished to the SEC. The information on our websites is not part of this Annual Report and is not incorporated by reference into this report or any other filing we make with the SEC.

Item 1A. Risk Factors

Investing in our securities involves risks. Before you invest in our securities, you should carefully consider the risk factors below together with all of the other information included in this Annual Report. If any of the risks discussed herein were to occur, our business, prospects, liquidity, financial condition, and results of operations could be materially impaired. In such case, the market price of our Class A common stock could decline, and you may lose some or all of your investment. The disclosures in this section reflect our beliefs and opinions as to factors that could materially and adversely affect us in the future. References to past events are provided by way of example only and are not intended to be a complete listing or a representation as to whether or not such factors have occurred in the past. Some statements in this Annual Report, including statements in the following risk factors, constitute forward-looking statements. See "Cautionary Note Regarding Forward-Looking Statements" for additional information.

Risks Related to Our Business, Industry, and Operations

Our global operations are subject to inherent risks that could materially adversely affect our business, results of operations, and financial condition.

Our global operations are subject to risks that may materially adversely affect our business, results of operations, and financial condition. We import a significant percentage of our Medline Brand products from outside of the United States, including 5% of our costs of goods sold from China for the year ended December 31, 2025. As a result of our global operations, we may experience, among other things:

- difficulties and costs relating to staffing and managing foreign operations;
- difficulties and delays inherent in sourcing products, establishing channels of distribution, and contract manufacturing in foreign markets;
- difficulties in ending foreign distribution relationships where the distributor exclusively or predominantly markets and sells Medline Brand products;
- concerns related to transparency regarding extended international supply chains and labor risk based on sourcing footprint, including compliance with labor and human rights laws, that might arise despite reasonable efforts to mitigate this risk;
- fluctuations in the value of foreign currencies;
- uncertainties relating to trade agreements and international trade relationships;
- longer payment cycles of foreign customers and difficulty of collecting receivables in foreign jurisdictions;
- difficulties repatriating cash from our foreign operations to the United States;
- legal and regulatory requirements including, without limitation, compliance with the FCPA; UK bribery laws and similar anti-bribery, anti-corruption, and economic sanctions laws and regulations; laws pertaining to the accuracy of our internal books and records; and environmental, health, and safety laws and regulations;
- litigation risks, new or unanticipated litigation developments, and the status of litigation matters;
- unexpected difficulties in importing or exporting our products and trade laws, import/export tariffs, quotas, sanctions, or penalties, custom duties, and other trade restrictions;

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 3 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

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

Provide explanation below:

See Attachment 1 for corporate disciplinary history.

Previously reviewed & Approved

Original Signature (electronic, copies or stamps not accepted)

07/14/2026
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	08/03/2005	MO	Kansas City	Jackson
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2003031660		Missouri Board of Pharmacy		
Reason/Charge				
Failure to Renew on Time; Temperature Control Deficiency				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
MO Board of Pharmacy/ Medline Industries, Inc.			Administrative Action	
Name of Business/Industry/Entity				
Medline Industries, Inc.				

Provide explanation below:

Medline Industries Inc. distribution center at 1401 N. Universal Ave, Kansas City, MO 64120 (MO# DD2003031660) cited for failure to renew on time and deficient temperature control procedures. All issues resolved via Settlement Agreement effective 08/03/2005. License placed on probation for 5 years. The state conducted multiple inspections of the facility throughout the probationary period and found Medline to comply with all requirements. The probationary period closed in August 2010.

Corrective Actions:
Medline hired additional staff to monitor and ensure on-time license renewal. A temperature control room was constructed at the facility to ensure products are stored at the appropriate temperature and humidity.

Attachment 1a

Original Signature (electronic, copies or stamps not accepted)

7/14/26
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	12/07/2006	GA	Lithia Springs	Douglas

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
N/A	Florida Department of Health

Reason/Charge
Medline's Florida Certified Designated Representative unexpectedly resigned.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Florida Department of Health/ Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries Inc. distribution center at 9101 Riverside Pkwy Lithia Springs, GA 30122 Non-Resident FL Permit (FL # 23:1470) suspended for operating without a FL Certified Designated Representative. The CDR resigned unexpectedly. Upon receipt of the notice of intent to suspend, Medline stopped all shipments into the state of FL. Permit was reinstated upon hiring of a new licensed Florida CDR.

Corrective Actions:
Qualified FL Certified Designated Representative hired for facility. Medline implemented a policy requiring all FL licensed distribution centers to maintain a backup Florida Certified Designated Representative on staff.

Attachment 16

Original Signature (electronic, copies or stamps not accepted)

7/17/20
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	02/08/2008	FL	Gainesville	Alachua
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2007-37412		Florida Department of Health		
Reason/Charge				
Inspection Deficiencies				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Florida Department of Health / Medline Industries, Inc.			Administrative Action	
Name of Business/Industry/Entity				
Medline Industries, Inc.				

Provide explanation below:

Medline Industries, Inc. distribution center at 2708 NE Waldo Rd., Gainesville, FL 32609 FL Permit (FL # 22:1022) suspended for violations identified during a Florida BOP facility inspection. Medline, through Counsel, addressed the issues raised in the inspection and established that the suspension was unjustified. The suspension was lifted 3 days later on January 22, 2008. Medline Industries, Inc. entered into a settlement agreement on 02/08/2008 with the FL Department of Health to resolve all issues related to the case.

Corrective Actions:
Medline conducted a thorough review of its policies and procedures and implemented an internal auditing program to ensure that all distribution centers comply with internal policies and procedures and state and federal regulations.

Attachment 1c

Original Signature (electronic, copies or stamps not accepted)

7/14/26
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	05/01/2008	LA	Covington	St. Tammany Parish

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2008006	Louisiana Board of Wholesale Drug Distributors

Reason/Charge
Customer Licenses

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
LA Board of WDD/ Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries Inc. distribution center at 149 New Camellia Blvd. Covington, LA 70433 (LA #4318) cited for failure to properly maintain copies of current customer licenses on-site. Licenses were maintained by Medline's Regulatory team at corporate headquarters. Medline entered a consent decree effective 05/01/2008 to resolve the alleged violation.

Corrective Actions:
Medline implemented digital storage of customer licenses to allow for on-demand access by distribution centers.

Attachment 1d

Original Signature (electronic, copies or stamps not accepted)

7/14/20
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	07/08/2008	HI	Waipahu	Honolulu
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
PHA 2008-71-L		Hawaii Department of Commerce and Consumer Affairs		
Reason/Charge				
Late Discipline Reporting				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
HI DCCA / Medline Industries, Inc.			Administrative Action	
Name of Business/Industry/Entity				
Medline Industries, Inc.				

Provide explanation below:

Medline Industries, Inc. distribution center at 94-1420 Moaniani St., Waipahu, HI 96797 (HI # PWD 115) entered a settlement agreement and placed on probation for 5 years for failure to report disciplinary actions within 30 days. Medline submitted all required notices but missed the 30-day deadline. The probationary period ended in August 2013.

Corrective Actions:
Medline implemented a policy and procedure to notify licensing boards of disciplinary actions within the required reporting timelines.

Attachment

Original Signature (electronic, copies or stamps not accepted)

7/14/26
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	9/06/2008	FL	Multiple	Multiple
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
See Below		Florida Department of Health		
Reason/Charge				
Pedigree, Incorrect Permit, Distribution to Unauthorized Receipt, Storage				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
FL DOH / Medline Industries, Inc.			Administrative Action	
Name of Business/Industry/Entity				
Medline Industries, Inc.; Medline Manufacturing & Services, LLC				

Provide explanation below:

Medline Industries Inc. and Medline Manufacturing & Services, LLC was cited for several violations related to distribution centers in Florida, including, failure to pass and maintain a Florida compliant pedigree, maintaining the wrong permit type for the activities performed (Florida required a repackager permit in addition to the existing manufacturer permit), distribution of saline to an unauthorized recipient, and storage of a prescription drug in an unlicensed raw materials storage facility. Medline challenged several violations, resulting in most being substantially reduced or removed. All issues were addressed and resolved to the satisfaction of the FL DOH. A settlement agreement was reached to resolve all matters and approved on 09/06/2008.

Corrective Actions
Medline instituted a Florida specific pedigree system to address the pedigree issues. The updated pedigree ensures that all applicable shipments to Florida have the required Florida documentation and comply with FL pedigree requirements (Note - these requirements have since been preempted by the federal Drug Supply Chain Security Act). Medline secured the repackaging permit to address the missing permit type. Medline instituted a new procedure for obtaining and maintaining customer licenses for all prescription drug purchases- this procedure generates an automatic block for any prescription drug order by an unlicensed customer. The prescription drug item unintentionally stored in the raw materials facility was properly disposed of and waste disposal procedures updated to prevent this from occurring in the future.

Locations:
10601 Southport Dr., Orlando, FL 32824
401 Commerce Blvd, Oldsmar, FL 34677
4750 118th Ave N, Clearwater, FL 33762

Case #: 2007-11783; 2007-36555; 2007-38894; 2007-38895; 2007-38896; 2007-39073; 2008-02011; 2008-11215

Attachment 1f

Original Signature (electronic, copies or stamps not accepted)

7/19/26
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	02/04/2009	WI	Wausau	Marathon

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
08 PHM 037	Wisconsin Department of Regulation and Licensing

Reason/Charge
Failure to Separate Products, Failure to retrieve Policies and Procedure during Inspection

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
WI DSPS/ Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries Inc. distribution center at 5450 W. Stewart Ave., Wausau, WI 54401 (WI # 1116-045) cited for missing policies and procedures and storage of drugs in a non-secure location following an inspection by the Wisconsin Department of Regulation & Licensing. Medline managed a portion of a Wisconsin hospital's warehouse. The inspector cited Medline for failure to install a dividing fence between the Medline warehouse and the hospital portion of the facility. All hospital products were owned by the hospital. Medline was also cited for failure to access policies and procedures during the inspection. Corrections were made and the facility re-inspected, to the satisfaction of the state. Medline entered a stipulation order effective 02/04/2009 to resolve the matter.

Corrective Actions:
Medline installed a locked fence to separate the hospital's owned products. Medline also completed a review of all facilities to ensure proper separation of products. On-site staff provided additional training on how to access current policies and procedures during an inspection.

Attachment 1g

Original Signature (electronic, copies or stamps not accepted)

7/19/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	05/19/2009	HI	Waipahu	Honolulu

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
PHA 2009-7-L	Hawaii Department of Commerce and Consumer Affairs

Reason/Charge
Discipline incurred in another jurisdiction

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
HI DCCA / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. agreed to enter a Consent Order for discipline incurred in another jurisdiction (Wisconsin Case #: 08 PHM 037).

Attachment 1N

Original Signature (electronic, copies or stamps not accepted)

7/14/26
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	03/19/2010	MO	Kansas City	Jackson

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2010-002994	Colorado State Board of Pharmacy

Reason/Charge
Conditional License

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
CO Board of Pharmacy / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. distribution center at 1401 N. Universal Ave, Kansas City, MO 64120 applied for a Colorado Out-of-State Wholesaler license. The CO Board of Pharmacy issued a conditional license until the facility's MO probation period ended. (See Case 2003031660 above). Medline informed the CO Board when the MO probationary period was completed. Upon completion of probation, the Board issued a full license.

Corrective Actions:
Medline successfully completed terms of probation in MO and CO.

Attachment li

Original Signature (electronic, copies or stamps not accepted)

7/14/26
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	7/18/2014	NY	Middletown	Orange

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
27278	NY State Education Department- Board of Pharmacy

Reason/Charge
Discipline incurred in another jurisdiction

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
NY Board of Pharmacy / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. agreed to enter a Consent Order for discipline incurred in another jurisdiction (FL No. 2007-37412, LA No. 2008006, and WI No. 08 PHM 037).

Corrective Actions:
See corrective actions for FL No. 2007-37412, LA No. 2008006, and WI No. 08 PHM 037.

Attachment lj

Original Signature (electronic, copies or stamps not accepted)

7/14/26
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	01/06/2021	IL	Libertyville	Lake

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
A-2020-0054	Ohio Board of Pharmacy

Reason/Charge
Customer License

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Ohio Board of Pharmacy / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. distribution center at 1501 Harris Rd Libertyville, IL 60048 (OH License #01-1985050) entered into a settlement agreement with the Ohio Board of Pharmacy for the sale of dangerous drugs to an unlicensed entity. Medline maintained a current and valid DEA license on file rather than the correct Terminal Distributor Dangerous Drugs license (TDDD). The facility's TDDD license expired at the time of the sale. Case resolved via Settlement Agreement effective 01/06/2021.

Corrective Actions:
Medline updated its customer license requirements for Ohio customers. Medline completed a review of all Ohio customers to verify the correct license type was on file and implemented increased verification checks of Ohio licenses.

Attachment 1k

Original Signature (electronic, copies or stamps not accepted)

7/14/26
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	06/28/2021	IL	Libertyville	Lake
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
21-L-0048		Alabama Board of Pharmacy		
Reason/Charge				
Discipline incurred in another jurisdiction				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Alabama Board of Pharmacy / Medline Industries, Inc.			Administrative Action	
Name of Business/Industry/Entity				
Medline Industries, Inc.				

Provide explanation below:

Medline Industries, Inc. distribution center at 1501 Harris Rd Libertyville, IL 60048 (AL Non-Resident Permit #193718) was fined for discipline incurred in another jurisdiction (OH A-2020-0054).

Attachment 1L

Original Signature (electronic, copies or stamps not accepted)

7/14/20
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	11/01/2022	OH	West Jefferson	Madison
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
A-2022-0333		Ohio Board of Pharmacy		
Reason/Charge				
Customer Licenses				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Ohio Board of Pharmacy / Medline Industries, LP			Administrative Action	
Name of Business/Industry/Entity				
Medline Industries, LP				

Provide explanation below:

Medline Industries, LP distribution center at 1040 Enterprise Parkway South, West Jefferson, OH 43162 (OH License #01-30000190) entered a settlement agreement with the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file instead of the correct Terminal Distributor Dangerous Drugs license (TDDD). The TDDD license was added in May 2022. During the period of July 2021 to March 2022, the customer's TDDD license lapsed, and Medline shipped the customer product under the valid practitioner license. Case resolved via Settlement Agreement effective 11/01/2022.

Corrective Actions:
Medline updated customer licensing requirements for Ohio customers following OH Case # A-2020-0054. The shipments in this matter occurred while Medline was in the process of reviewing and updating all Ohio customer licenses. Medline licensing staff were also provided with additional training on Ohio license requirements.

Attachment Im

Original Signature (electronic, copies or stamps not accepted)

7/14/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	12/19/2022	FL	Miami	Miami-Dade

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
A-2022-0333	FL DBPR- Div. of Drugs, Devices, and Cosmetics

Reason/Charge
Customer Licenses, Record Keeping

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
FL DBPR / Medline Industries, LP	Administrative Action

Name of Business/Industry/Entity
Medline Industries, LP

Provide explanation below:

Medline Industries, LP distribution center at 9670 NW 112th Ave, Miami, FL 33178 (FL WDD# #2220297) entered a settlement agreement for alleged violations of selling prescription drugs to an unauthorized recipient and failure to maintain proper records. Medline accepted a physician license for a customer which should have maintained a Healthcare Clinic Establishment Permit. The recordkeeping allegation related to missing NDC numbers on outbound packing slips and invoices.

Corrective Actions:
Medline updated customer licensing requirements for Florida customers and completed an extensive review of all FL customer licenses to verify the correct license type was on file. Medline determined the missing NDC number on the packing slip and invoice occurred due to an internal system error. The error was limited to DSCSA exempt products, i.e. IV fluids. A fix was implemented to correct the issue.

Attachment 1n

Original Signature (electronic, copies or stamps not accepted)

7/17/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	07/25/2023	OH/IN	See Below	See Below

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
A-2022-0307; A-2022-0184	Ohio Board of Pharmacy

Reason/Charge
Customer Licenses

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Ohio Board of Pharmacy / Medline Industries, LP	Administrative Action

Name of Business/Industry/Entity
Medline Industries, LP

Provide explanation below:

Medline Industries, LP distribution centers at 1040 Enterprise Parkway South, West Jefferson, OH 43162 (OH License #01-30000190) and 251 Hilton Drive. Jeffersonville, IN 47130 (OH License #01-30000158) entered settlement agreements with the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. The sales occurred between July 2021 and January 2022. Medline maintained valid practitioner licenses on file for each customer instead of the correct d sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file instead of the correct Terminal Distributor Dangerous Drugs license (TDDD). Cases resolved via Settlement Agreement effective 07/19/2023 and 07/25/2023.

Corrective Actions:
Medline updated customer licensing requirements for Ohio customers following OH Case # A-2020-0054. The shipments in this matter occurred between July 2021 and January 2022 while Medline was in the process of reviewing and updating all Ohio customer licenses.

Locations:
1040 Enterprise Parkway South, West Jefferson, OH 43162 (Madison County)
251 Hilton Drive, Jeffersonville, IN 47130 (Clark County)

Attachment 10

Original Signature (electronic, copies or stamps not accepted)

7/19/24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	12/21/2023	HI	Kapolei	Honolulu
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
PHA 2023-9-L		Hawaii Department of Commerce and Consumer Affairs		
Reason/Charge				
Discipline incurred in another jurisdiction				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
HI DCCA / Medline Industries, LP		Administrative Action		
Name of Business/Industry/Entity				
Medline Industries, LP				

Provide explanation below:

Medline Industries, LP distribution center at 2341 Lauwiliwili St, Kapolei, HI 96707 (HI #) entered a Settlement Agreement for discipline incurred in another jurisdiction (OH A-2022-0333, OH A-2022-0307, OH A-2022-0184, and FL 2022-031132)

Attachment 1p

Original Signature (electronic, copies or stamps not accepted)

07/14/26
Date

Medline Industries, LP- Discipline *Confidential* Attachment 1

Date of Resolution	Facility	Description
08/03/2005	1401 N. Universal Ave Kansas City, MO 64120	**Case:** 2003031660 **Agency:** Missouri Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement, 5 years' probation **Summary:** Medline Industries Inc. distribution center at 1401 N. Universal Ave, Kansas City, MO 64120 (MO# DD2003031660) cited for failure to renew on time and deficient temperature control procedures. All issues resolved via Settlement Agreement effective 08/03/2005. License placed on probation for 5 years. The state conducted multiple inspections of the facility throughout the probationary period and found Medline to comply with all requirements. The probationary period closed in August 2010. **Corrective Actions:** Medline hired additional staff to monitor and ensure on-time license renewal. A temperature control room was constructed at the facility to ensure products are stored at the appropriate temperature and humidity.
12/07/2006	9101 Riverside Pkwy Lithia Springs, GA 30122	**Case:** N/A **Agency:** Florida Department of Health **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Temporary Suspension Lifted **Summary:** Medline Industries Inc. distribution center at 9101 Riverside Pkwy Lithia Springs, GA 30122 Non-Resident FL Permit (FL # 23:1470) suspended for operating without a FL Certified Designated Representative. The CDR resigned unexpectedly. Upon receipt of the notice of intent to suspend, Medline stopped all shipments into the state of FL. Permit was reinstated upon hiring of a new licensed Florida CDR. **Corrective Actions:** Qualified FL Certified Designated Representative hired for facility. Medline implemented a policy requiring all FL licensed distribution centers to maintain a backup Florida Certified Designated Representative on staff.
02/08/2008	2708 NE Waldo Rd. Gainesville, FL 32609	**Case:** 2007-37412 **Agency:** Florida Department of Health **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement **Summary:** Medline Industries, Inc. distribution center at 2708 NE Waldo Rd., Gainesville, FL 32609 FL Permit (FL # 22:1022) suspended for violations identified during a Florida BOP facility inspection. Medline, through Counsel, addressed the issues raised in the inspection and established that the suspension was unjustified. The suspension was lifted 3 days later on January 22, 2008. Medline Industries, Inc. entered into a settlement agreement on 02/08/2008 with the FL Department of Health to resolve all issues related to the case. **Corrective Actions:** Medline conducted a thorough review of its policies and procedures and implemented an internal auditing program to ensure that all distribution centers comply with internal policies and procedures and state and federal regulations.
05/01/2008	149 New Camellia Blvd. Covington, LA 70433	**Case:** 2008006 **Agency:** Louisiana Board of Wholesale Drug Distributors **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Consent Decree **Summary:** Medline Industries Inc. distribution center at 149 New Camellia Blvd. Covington, LA 70433 (LA #4318) cited for failure to properly maintain copies of current customer licenses on-site. Licenses were maintained by Medline's Regulatory team at corporate headquarters. Medline entered a consent decree effective 05/01/2008 to resolve the alleged violation. **Corrective Actions:** Medline implemented digital storage of customer licenses to allow for on-demand access by distribution centers.

07/08/2008	94-1420 Moaniani St. Waipahu, HI 96797	**Case #:** PHA 2008-71-L **Agency:** Hawaii Department of Commerce and Consumer Affairs **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, Inc. distribution center at 94-1420 Moaniani St., Waipahu, HI 96797 (HI # PWD 115) entered a settlement agreement and placed on probation for 5 years for failure to report disciplinary actions within 30 days. Medline submitted all required notices but missed the 30-day deadline. The probationary period ended in August 2013. **Corrective Actions:** Medline implemented a policy and procedure to notify licensing boards of disciplinary actions within the required reporting timelines.
09/06/2008	10601 Southport Dr. Orlando, FL 32824 _____ 401 Commerce Blvd. Oldsmar, FL 34677 _____ 4750 118th Ave N Clearwater, FL 33762	**Case #:** 2007-11783; 2007-36555; 2007-38894; 2007-38895; 2007-38896; 2007-39073; 2008-02011; 2008-11215 **Agency:** Florida Department of Health **Entity:** Medline Industries, Inc.; Medline Manufacturing & Services, LLC **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries Inc. and Medline Manufacturing & Services, LLC was cited for several violations related to distribution centers in Florida, including, failure to pass and maintain a Florida compliant pedigree, maintaining the wrong permit type for the activities performed (Florida required a repackager permit in addition to the existing manufacturer permit), distribution of saline to an unauthorized recipient, and storage of a prescription drug in an unlicensed raw materials storage facility. Medline challenged several violations, resulting in most being substantially reduced or removed. All issues were addressed and resolved to the satisfaction of the FL DOH. A settlement agreement was reached to resolve all matters and approved on 09/06/2008. **Corrective Actions** Medline instituted a Florida specific pedigree system to address the pedigree issues. The updated pedigree ensures that all applicable shipments to Florida have the required Florida documentation and comply with FL pedigree requirements (Note - these requirements have since been preempted by the federal Drug Supply Chain Security Act). Medline secured the repackaging permit to address the missing permit type. Medline instituted a new procedure for obtaining and maintaining customer licenses for all prescription drug purchases- this procedure generates an automatic block for any prescription drug order by an unlicensed customer. The prescription drug item unintentionally stored in the raw materials facility was properly disposed of and waste disposal procedures updated to prevent this from occurring in the future.
02/04/2009	5450 W. Stewart Ave. Wausau, WI 54401	**Case:** 08 PHM 037 **Agency:** Wisconsin Department of Regulation and Licensing **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Stipulation Order **Summary:** Medline Industries Inc. distribution center at 5450 W. Stewart Ave., Wausau, WI 54401 (WI # 1116-045) cited for missing policies and procedures and storage of drugs in a non-secure location following an inspection by the Wisconsin Department of Regulation & Licensing. Medline managed a portion of a Wisconsin hospital's warehouse. The inspector cited Medline for failure to install a dividing fence between the Medline warehouse and the hospital portion of the facility. All hospital products were owned by the hospital. Medline was also cited for failure to access policies and procedures during the inspection. Corrections were made and the facility re-inspected, to the satisfaction of the state. Medline entered a stipulation order effective 02/04/2009 to resolve the matter. **Corrective Actions:** Medline installed a locked fence to separate the hospital's owned products. Medline also completed a review of all facilities to ensure proper separation of products. On-site staff provided additional training on how to access current policies and procedures during an inspection.

05/19/2009	94-1420 Moaniani St. Waipahu, HI 96797	**Case:** PHA 2009-7-L **Agency:** Hawaii Department of Commerce and Consumer Affairs **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, Inc. agreed to enter a Consent Order for discipline incurred in another jurisdiction (Wisconsin Case #: 08 PHM 037). **Corrective Actions:** See Corrective Actions for Case #: 08 PHM 037.
03/19/2010	1401 N. Universal Ave. Kansas City, MO 64120	**Case:** 2010-002994 **Agency:** Colorado State Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Stipulation **Summary:** Medline Industries, Inc. distribution center at 1401 N. Universal Ave, Kansas City, MO 64120 applied for a Colorado Out-of-State Wholesaler license. The CO Board of Pharmacy issued a conditional license until the facility's MO probation period ended. (See Case 2003031660 above). Medline informed the CO Board when the MO probationary period was completed. Upon completion of probation, the Board issued a full license. **Corrective Actions:** Medline successfully completed terms of probation in MO and CO.
07/18/2014	3301 Route 6 Middletown, NY 10940	**Case:** 27278 **Agency:** NY State Education Department- Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Consent Order **Summary:** Medline Industries, Inc. agreed to enter a Consent Order for discipline incurred in another jurisdiction (FL No. 2007-37412, LA No. 2008006, and WI No. 08 PHM 037). **Corrective Actions:** See corrective actions for FL No. 2007-37412, LA No. 2008006, and WI No. 08 PHM 037.
01/06/2021	1501 Harris Rd Libertyville, IL 60048	**Case:** A-2020-0054 **Agency:** Ohio Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, Inc. distribution center at 1501 Harris Rd Libertyville, IL 60048 (OH License #01-1985050) entered into a settlement agreement with the Ohio Board of Pharmacy for the sale of dangerous drugs to an unlicensed entity. Medline maintained a current and valid DEA license on file rather than the correct Terminal Distributor Dangerous Drugs license (TDDD). The facility's TDDD license expired at the time of the sale. Case resolved via Settlement Agreement effective 01/06/2021. **Corrective Actions:** Medline updated its customer license requirements for Ohio customers. Medline completed a review of all Ohio customers to verify the correct license type was on file and implemented increased verification checks of Ohio licenses.

06/28/2021	1501 Harris Rd Libertyville, IL 60048	**Case:** 21-L-0048 **Agency:** Alabama Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Order **Summary:** Medline Industries, Inc. distribution center at 1501 Harris Rd Libertyville, IL 60048 (AL Non-Resident Permit #193718) was fined for discipline incurred in another jurisdiction (OH A-2020-0054) **Corrective Actions:** See corrective action for OH A-2020-0054.
11/01/2022	1040 Enterprise Parkway South West Jefferson, OH 43162	**Case:** A-2022-0333 **Agency:** Ohio Board of Pharmacy **Entity:** Medline Industries, LP **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, LP distribution center at 1040 Enterprise Parkway South, West Jefferson, OH 43162 (OH License #01-30000190) entered a settlement agreement with the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file instead of the correct Terminal Distributor Dangerous Drugs license (TDDD). The TDDD license was added in May 2022. During the period of July 2021 to March 2022, the customer's TDDD license lapsed, and Medline shipped the customer product under the valid practitioner license. Case resolved via Settlement Agreement effective 11/01/2022. **Corrective Actions:** Medline updated customer licensing requirements for Ohio customers following OH Case # A-2020-0054. The shipments in this matter occurred while Medline was in the process of reviewing and updating all Ohio customer licenses. Medline licensing staff were also provided with additional training on Ohio license requirements.
12/19/2022	9670 NW 112th Ave Miami, FL 33178	**Case:** 2022-031132 **Agency:** FL Dept. Business and Professional Regulation, Div. of Drugs, Devices, and Cosmetics **Entity:** Medline Industries, LP **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, LP distribution center at 9670 NW 112th Ave, Miami, FL 33178 (FL WDD# #2220297) entered a settlement agreement for alleged violations of selling prescription drugs to an unauthorized recipient and failure to maintain proper records. Medline accepted a physician license for a customer which should have maintained a Healthcare Clinic Establishment Permit. The recordkeeping allegation related to missing NDC numbers on outbound packing slips and invoices. **Corrective Actions:** Medline updated customer licensing requirements for Florida customers and completed an extensive review of all FL customer licenses to verify the correct license type was on file. Medline determined the missing NDC number on the packing slip and invoice occurred due to an internal system error. The error was limited to DSCSA exempt products, i.e. IV fluids. A fix was implemented to correct the issue.

07/19/2023 07/25/2023	1040 Enterprise Parkway South West Jefferson, OH 43162 _____ 251 Hilton Drive Jeffersonville, IN 47130	**Case:** A-2022-0307; A-2022-0184 **Agency:** Ohio Board of Pharmacy **Entity:** Medline Industries, LP **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, LP distribution centers at 1040 Enterprise Parkway South, West Jefferson, OH 43162 (OH License #01-30000190) and 251 Hilton Drive. Jeffersonville, IN 47130 (OH License #01-30000158) entered settlement agreements with the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. The sales occurred between July 2021 and January 2022. Medline maintained valid practitioner licenses on file for each customer instead of the correct d sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file instead of the correct Terminal Distributor Dangerous Drugs license (TDDD). Cases resolved via Settlement Agreement effective 07/19/2023 and 07/25/2023. **Corrective Actions:** Medline updated customer licensing requirements for Ohio customers following OH Case # A-2020-0054. The shipments in this matter occurred between July 2021 and January 2022 while Medline was in the process of reviewing and updating all Ohio customer licenses.
12/21/2023	2341 Lauwiliwili St. Kapolei, HI 96707	**Case:** PHA 2023-9-L **Agency:** Hawaii Department of Commerce and Consumer Affairs **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, LP distribution center at 2341 Lauwiliwili St, Kapolei, HI 96707 (HI #) entered a Settlement Agreement for discipline incurred in another jurisdiction (OH A-2022-0333, OH A-2022-0307, OH A-2022-0184, and FL 2022-031132) **Corrective Actions:** See corrective actions for OH A-2022-0333, OH A-2022-0307, OH A-2022-0184, and FL 2022-031132.

Attachment 1a

Jeremiah W. (Jay) Nixon
Governor
State of Missouri

Jane A. Rackers, Division Director
DIVISION OF PROFESSIONAL REGISTRATION

Department of Insurance
Financial Institutions
and Professional Registration
John M. Huff, Director

MISSOURI BOARD OF PHARMACY
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573-751-0091 PHONE
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kimberly A. Grinston
Executive Director
www.pr.mo.gov/pharmacists.asp
e-mail: pharmacy@pr.mo.gov

08/03/2010

Charlie Mills
One Medline Place
Mundelein, IL 60060-4486

Dear Mr. Mills,

This is official notification that you have completed your terms of Probation with the Missouri Board of Pharmacy as of August 2, 2010.

If you have any questions, or if we can be of assistance in the future, feel free to contact this office. Thank you for complying.

Sincerely,

Jason Menken
Compliance Coordinator
Missouri Board of Pharmacy

Matt Blunt, Governor
State of Missouri

Alison Craighead, Director
Division of Professional Registration

Gregory A. Steinhoff, Director
Department of Economic Development

BOARD OF PHARMACY
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, MO 65102-0625
573-751-0091
573-526-3464 FAX
800-735-2966 TTY Relay Missouri
800-735-2466 Voice Relay Missouri

Kevin E. Kinkade, R.Ph.
Executive Director

www.pr.mo.gov/pharmacists.asp
e-mail: pharmacy@pr.mo.gov

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
7160 3901 9848 6160 3154

August 4, 2005

Mr. Pete Furlong, Corporate Vice President
Quality Assurance/Regulatory Affairs
Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060-4486

Dear Mr. Furlong:

Enclosed is an executed copy of the **Settlement Agreement Between State Board of Pharmacy and Medline Industries, Inc.** A permanent drug distributor license, numbered 2003031660, has been issued to Medline Industries, Inc., 1401 N Universal Avenue, Kansas City, MO, and is being mailed to the facility with a copy of this letter. That license has been placed on probation August 3, 2005, through August 2, 2010.

A 2005-2007 Drug Distributor Renewal Application will be mailed to the facility within the next two weeks. This form must be completed and returned with the $400.00 fee before October 31, 2005.

You should review each term of this Agreement and comply with the requirements as set forth. Compliance is your responsibility; reminders will not be sent from this office. Licensee Report of Discipline Compliance forms are being included with the mailing to the facility and should be completed and submitted to the Board office within six months from the beginning of the probation period and every six months following that for the duration of the probation. Failure to comply with the terms of this Agreement may result in a violation hearing before the Board.

If you have any questions, please feel free to contact this office at 573-751-9056.

Sincerely,

DON WALKER
Drug Distributor Coordinator

Enclosures
cc: Rob Angstead, Attorney
Scott C Barbour, Manager-in-Charge

SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND MEDLINE INDUSTRIES, INC.

Come now Medline Industries, Inc. ("Respondent") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's license as a drug distributor will be subject to discipline.

Pursuant to the terms of § 536.060, RSMo (2000), the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under § 621.110, RSMo (2000), and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by legal counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its license. Being aware of these rights provided it by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document, as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the Board, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's license. For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this

Settlement Agreement are true and stipulates with the Board that Respondent's temporary license as a drug distributor, License Number DD2003031660, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo 2000. The parties agree that this Settlement Agreement and any statements contained herein may not be used for or constitute an admission for any purposes other than to settle the disputes between the parties.

Joint Stipulation of Facts

1. Petitioner, the Missouri Board of Pharmacy ("the Board"), is an agency of the State of Missouri created and established by § 338.110, RSMo (2000), for the purpose of administering and enforcing the provisions of Chapter 338, RSMo.

2. Respondent, Medline Industries, Inc., located at 4700 Deramus, Kansas City, Missouri, is licensed by the Board as a drug distributor under the laws of Missouri, License Number DD2003031660. The license is current and active.

3. On or about April 16, 1996, Wilson Winch, an inspector for the Board, conducted an inspection at the facility located at 1691 N. Topping, Kansas City, Missouri.

4. Inspector Winch noted on the Drug Distributor Inspection Observation Report that Respondent needed temperature/humidity recording equipment and that the results must be logged daily.

5. On or about August 8, 1997, Tom Glenski, an inspector for the Board, conducted an inspection at the facility located at 1250 N. Southern, Kansas City, Missouri.

6. Inspector Glenski noted on the Drug Distributor Inspection Observation Report that Respondent needed a temperature and humidity daily log.

7. On or about September 3, 1997, the Board received a written response dated August 27, 1997, from Lara Simmons, Respondent's Director of Regulatory Affairs, explaining that a temperature and humidity monitoring device was being purchased and the temperature and humidity will be recorded daily during days of operation.

8. Ms. Simmons indicated that she anticipated the temperature and humidity monitoring device would be in place and the recordkeeping started by the first of September, 1997.

9. On or about July 31, 1998, Inspector Tom Glenski conducted an inspection at the facility located at 1250 N. Southern, Kansas City, Missouri.

10. Inspector Glenski noted on the Drug Distributor Inspection Observation Report that Respondent needed to keep daily temperature and humidity recordings.

11. Respondent failed to purchase the temperature and humidity monitoring device as Ms. Simmons indicated would be purchased.

12. Respondent's failure to provide an appropriate temperature and humidity monitoring device is in violation of 21 CFR § 211.46(b) which states:

> (b) Equipment for adequate control over air pressure, micro-organisms, dust, humidity, and temperature shall be provided when appropriate for the manufacture, processing, packing, or holding of a drug product.

13. On September 9, 1998, the Board sent a Compliance Letter to Respondent for a number of non-compliance issues found on the July 31, 1998 inspection, one of which was "temperature/humidity daily log documentation".

14. On or about September 2, 1999, Inspector Glenski conducted an inspection at the facility located at 1250 N. Southern, Kansas City, Missouri.

15. Inspector Glenski noted on the Drug Distributor Inspection Observation Report that the warehouse temperature exceeded the manufacturer's recommended storage temperature of 86 degrees Fahrenheit.

16. On or about October 4, 2000, Inspector Glenski conducted an inspection at the facility located at 1250 N. Southern, Kansas City, Missouri.

17. Inspector Glenski noted on the Drug Distributor Inspection Observation Report that the temperature exceeded 86 degrees on various days between July, 2000 and September, 2000.

18. On or about September 20, 2001, Frank Van Fleet, an inspector for the Board, conducted a change-of-location inspection at the facility located at 4700 Deramus, Kansas City, Missouri.

19. Inspector Van Fleet noted on the Observation Report that the temperature exceeds 86 degrees on not less than 32 occasions between June 8, 2001 and September 5, 2001.

20. On or about May 21, 2003, Inspector Van Fleet conducted an inspection at the facility located at 4700 Deramus, Kansas City, Missouri.

21. Inspector Van Fleet noted on the Observation Report that the temperature exceeded 86 degrees on not less than 41 occasions between June 3, 2002 and September 30, 2002.

22. On or about August 19, 2003, Inspector Van Fleet conducted a follow-up inspection at the facility located at 4700 Deramus, Kansas City, Missouri.

23. Inspector Van Fleet monitored storage temperatures with a digital thermometer at various locations where prescription product was stored.

24. Three additional occasions were identified between September 30, 2002 and August 19, 2003 where the temperature exceeded 86 degrees.

25. Inspector Van Fleet found that storage temperatures were much higher than the temperatures Respondent had recorded on its log.

26. Inspector Van Fleet's digital thermometer registered a range from 89.1 degrees in one area where Respondent stored bulk prescription hydrating/electrolyte solutions to as high as 94.5 degrees in Respondent's over the counter storage area, but Respondent's temperature log records a temperature of 89 degrees for this date.

27. Inspector Van Fleet presented at the 4700 Deramus facility on March 2, 2004 for tbe purpose of conducting a new facility inspection.

28. Inspector Van Fleet found 16 occasions between October 31, 2003 and February 27, 2004 where the temperature in the warehouse dropped below 59 degrees.

29. Respondent's warehouse is divided into three areas by breezeways.

30. Respondent has only one digital monitor for 120,000 square feet of warehouse.

31. The warehouse is not air-conditioned, and even though it is heated, logs show product was stored at less than 59 degrees.

32. Respondent has a history of noncompliance regarding the storage of prescription product.

33. Monitoring temperature and/or storing product at manufacturer's recommended/required humidity and storage temperature has been an issue on every inspection since 1996 involving three different locations and three different inspectors.

34. Respondent has been in at least three different warehouses in the last six years and

has failed each time to choose a warehouse that is temperature controlled.

35. Drugs must be stored in accordance with manufacturer or USP guidelines and must be free of contamination, deterioration and adulteration.

36. Drugs stored outside of manufacturer or USP guidelines can become contaminated, deteriorated and adulterated.

37. A drug shall be deemed adulterated pursuant to 21 USC 351(a)(2)(B) which states:

> A drug or device shall be deemed to be adulterated –
>
> > (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to the safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess . . .

38. Respondent's failure to maintain a facility where temperature is controlled and humidity is maintained is in violation of 4 CSR 220-5.030(3)(B) which states in pertinent parts:

> (3) Minimum standards of practice for drug distributors shall include the following:
>
> > (B) The temperature of the facility where drugs are stored must be maintained within temperature requirements as provided for by the manufacturer or the latest edition of the *United States Pharmacopeia* (USP). Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, logs, or all of these, shall be utilized to document proper storage of prescription drugs.

> (C) Appropriate housekeeping, sanitation, lighting, ventilation and humidity of all areas where drugs are stored must be maintained.

39. On or about April 16, 1997, Inspector Winch attempted an inspection at the facility located at 1691 N. Topping, Kansas City, Missouri and observed that Respondent had changed locations without notifying the Board.

40. Respondent's failure to timely notify the Board of its change of location and continue its operation as a wholesale drug distributor is in violation of 4 CSR 220-5.020(6) which states:

> (6) If an individual or business entity operating a drug distributor facility changes the location of the facility either within the existing facility (structure) or to a new facility (structure), the facility shall not open for business at the new location until the board, its duly authorized agent or the Food and Drug Administration has inspected the premises of the new location and approved it and the facility has been in compliance with all state and federal drug laws pertaining to drug distribution. Upon the approval and receipt of a change of location fee, the board shall issue a permit authorizing operation of a facility at the new location and the permit shall bear the same number as the previous license. However, the license remains valid if the facility address changes, but not the location, and an amended license will be issued without charge under these circumstances.

41. On or about August 8, 1997, Inspector Glenski conducted an inspection at the facility.

42. The inspector noted on the Drug Distributor Inspection Observation Report that Respondent needed a complete policy and procedure manual.

43. On or about September 2, 1999, Inspector Glenski conducted an inspection at the facility located at 1250 N. Southern, Kansas City, Missouri.

44. Inspector Glenski noted on the Drug Distributor Inspection Observation Report

that Respondent's policy and procedure manual could not be located.

45. Respondent's failure to establish and maintain a completed policy and procedure manual is in violation of 4 CSR 220-5.030(3)(M) which states in pertinent parts:

> (3) Minimum standards of practice for drug distributors shall include the following:
>
> > (M) Wholesale drug and pharmacy distributors shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts and for correcting all errors and inaccuracies in inventories.

46. On October 31, 2003, Respondent's drug distributor license expired.

47. Respondent failed to renew its license by the renewal deadline of November 30, 2003.

48. Respondent's license became null and void on November 30, 2003.

49. The Board received a new application from Respondent on or about December 16, 2003.

50. The Board issued Respondent temporary license number 2003031660 on December 29, 2003.

51. From the time Respondent's license became null and void on November 30, 2003, until the Board's issuance of Respondent's temporary license on December 29, 2003, Respondent failed to display a valid license.

52. Respondent's failure to display a valid license is in violation of 4 CSR 220-5.020(8)(B) which states:

> (B) A license must be posted in a conspicuous place in the

facility to which it is issued.

53. Respondent's invoice number 1016623706 shows the distribution of several Irrigation Solutions to Heart of America Surgery Center in Kansas City, Kansas on December 4, 2003.

54. Respondent's invoice number 1016626229 shows the distribution of an Irrigation Solution and Lactated Ringers IV Solution to Physician's Surgery Center in Rolla, Missouri on December 4, 2003.

55. Respondent's invoice number 1016648194 shows the distribution of Dextrose in Normal Saline IV Solution to Logan Manor Nursing Home in Logan, Kansas on December 6, 2003.

56. Respondent failed to renew its distributor license on or before November 30, 2003 and it became null and void at that time.

57. Respondent continued to distribute prescription only product while its license was expired.

58. Respondent's failure to renew its license by the renewal deadline of November 30, 2003 and to continue to distribute prescription only product while its license was expired is in violation of Section 338.333.1, RSMo (2000) states in pertinent part:

> 1. No person or distribution outlet shall act as a wholesale drug distributor or pharmacy distributor without first obtaining license to do so from the Missouri board of pharmacy and paying the required fee. . . . No license shall be issued or renewed for a wholesale drug distributor or pharmacy distributor to operate unless the same shall be operated in a manner prescribed by law and according to the rules and regulations promulgated by the board of pharmacy with respect thereto. Separate licenses shall be required for each distribution site owned or operated by a wholesale drug distributor or pharmacy distributor.

59. Respondent's opening for business its operation as a wholesale drug distributor in a new location prior to inspection and approval of the Board is in violation of 4 CSR 220-5.020(6) which states:

> (6) If an individual or business entity operating a drug distributor facility changes the location of the facility either within the existing facility (structure) or to a new facility (structure), the facility shall not open for business at the new location until the board, its duly authorized agent or the Food and Drug Administration has inspected the premises of the new location and approved it and the facility has been in compliance with all state and federal drug laws pertaining to drug distribution. Upon the approval and receipt of a change of location fee, the board shall issue a permit authorizing operation of a facility at the new location and the permit shall bear the same number as the previous license. However, the license remains valid if the facility address changes, but not the location, and an amended license will be issued without charge under these circumstances.

Joint Conclusions of Law

60. Cause exists for Petitioner to take disciplinary action against Respondent's license under § 338.353(1), RSMo (Supp. 2002) which provides:

> 1. The board of pharmacy is hereby authorized and empowered, when complaints, examinations or inspection of wholesale drug distributor or pharmacy distributor disclose to the board that a wholesale drug distributorship or pharmacy distributorship is not being operated or conducted according to such legal rules and regulations and the laws of Missouri or any other sate or the federal government with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621, RSMo, charging the holder of a license to operate a drug distributorship or pharmacy wholesale operation constituting grounds for discipline in accordance with section 338.055.

61. Cause exists to discipline Respondent' license as a drug distributor pursuant to the

provisions of § 338.055, RSMo (Supp. 2002) which provides in pertinent part:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his certificate of registration or authority, permit or license for any one or any combination of the following causes:
>
> * * *
>
> (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter.
>
> * * *
>
> (12) Failure to display a valid certificate or license if so required by this chapter or any rule promulgated hereunder.
>
> * * *
>
> (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government.

Joint Agreed Disciplinary Order

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of §621.045.3, RSMo (2000):

1. Respondent's drug distributor license shall be placed on PROBATION for five (5) years pursuant to the provisions of Chapters 338 and 620, RSMo. During the period of

probation, Respondent will be entitled to operate as a drug distributor pursuant to Chapter 338, RSMo provided Respondent adheres to the following terms of probation:

A. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months, beginning six (6) months after this Order/Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of this disciplinary order.

B. Respondent shall pay all required fees for licensing to the Board and shall renew its license prior to October 31 for each licensing year.

C. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

D. If, after disciplinary sanctions have been imposed, Respondent ceases to keep its Missouri license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

E. The parties to this Order/Agreement understand that the Board of Pharmacy will maintain this Order/Agreement as an open record of the Board as provided in Chapters 338, 610 and 620, RSMo.

2. Upon the expiration of said discipline, Respondent's license as a drug distributor in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary

hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent.

3. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

4. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

5. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

6. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and

attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to § 536.087, RSMo, or any claim arising under 42 U.S.C. § 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

_____ **REQUESTS**

_____ **DOES NOT REQUEST**

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S LICENSE TO OPERATE AS A DRUG DISTRIBUTOR.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's license and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for discipliming Respondent's license. Effective the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's license, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the

Settlement agreement goes into effect 15 days after the document is signed by the Board's Executive Director.

RESPONDENT

MEDLINE INDUSTRIES, INC.

By: _____
Pete Furlong
Corporate Vice President
Quality Assurance/Regulatory Affairs

Date: July 1, 2005

PETITIONER

MISSOURI BOARD OF PHARMACY

By: _____
Kevin Kinkade
Executive Director

Date: 7-19-05

HUSCH & EPPENBERGER, LLC

By: _____
Harvey M. Tettlebaum
235 East High Street
P.O. Box 1251
Jefferson City, MO 65102-1251
Telephone: 573/635-9118
Fax: 573/634-7854

Attorneys for Medline Industries, Inc.

NEWMAN, COMLEY & RUTH P.C.

By: _____
Robert K. Angstead #37795
601 Monroe, Suite 301
P.O. Box 537
Jefferson City, MO 65102-0537
Telephone: 573/634-2266
Fax: 573/636-3306

Attorneys for Missouri Board of Pharmacy

Attachment 1b

Medline Industries, Inc.
One Medline Place
Mundelein, Illinois 60060.4486
1.800.950.0128
Fax 1.847.949.2643

Corporate Quality Assurance/Regulatory Affairs

December 11, 2006

Ms. Rebecca R. Poston, R.Ph.
Executive Director
Drugs, Devices & Cosmetics Program
Florida Department of Health
4052 Bald Cypress Way
Tallahasee, FL 32399

RE: Prescription Drug Wholesaler Permit No. 23:01470

Dear Ms. Poston,

We have received the communication regarding the suspension of Prescription Drug Wholesaler Permit N. 23:01470. Pursuant to our communication with Rebecca Burnett on November 28, we have blocked applicable shipments from this location into Florida and they are being supplied by a properly permitted facility.

We are in the process of qualifying a replacement designated representative for this location. We hope to have this completed within the next 60 days.

Please note that Mr. Andy Stolarski is retiring and should no longer be listed as a contact for this location. Please direct any questions regarding this facility to
Ms. Lara Simmons
Corporate Director, Regulatory Affairs
One Medline Place
Mundelein, IL 60060
Phone: 847.837.2759
Fax: 847.837.2787
Email: LSimmons@Medline.com.

Sincerely,

Lara N. Simmons
Corporate Director, Regulatory Affairs

FLORIDA DEPARTMENT OF HEALTH

Jeb Bush
Governor

M. Rony François, M.D., M.S.P.H., Ph.D.
Secretary

CERTIFIED MAIL/RETURN RECEIPT REQUESTED

December 7, 2006

Andrew Stolarski
Vice President of Operations
Medline Industries, Inc.
9101 Riverside Parkway
Lithia Springs, GA 30122

RE: Prescription Drug Wholesaler Permit No. 23:01470

Dear Mr. Stolarski:

This letter serves as notification that the department intends to suspend permit no. 23:01470 issued to Medline Industries, Inc. as an Out of State Prescription Drug Wholesaler based upon the following facts, grounds and considerations:

Section 499.067(1)(a), Florida Statutes (F.S.), authorizes the department to deny, suspend, or revoke a permit if it finds that there has been substantial failure to comply with § 499.001-499.081, F.S., or Chapter 465, Chapter 501, or Chapter 893, the rules adopted under any of those sections or chapters, any final order of the department, or applicable federal laws or regulations or other state laws or rules governing drugs, devices, or cosmetics. The department may also suspend a permit if the applicant has not met the requirements for the permit.

Pursuant to s. 499.012(11)(a), F.S., each establishment that is issued an initial or renewal permit as a prescription drug wholesaler or an out-of-state prescription drug wholesaler must designate in writing to the department at least one natural person to serve as the designated representative of the wholesaler. Such person must have an active certification as a designated representative from the department and must also meet the requirements of Section 499.012 (11) (d) F.S.

Pursuant to s. 499.012(11)(f), F.S., a wholesale distributor may not operate under a prescription drug wholesaler permit or an out-of-state prescription drug wholesaler permit for more than 10 business days after the designated representative leaves the employ of the wholesale distributor, unless the wholesale distributor employs another designated representative and notifies the department within 10 business days of the identity of the new designated representative. Mr. David L. Magruder, the designated representative identified for permit no. 23:01470 has resigned his position. We have not received a "Notification of Designated Representative" form identifying a certified individual to replace him. As a result Medline Industries, Inc. does not have a designated representative as required by s. 499.012(11), F.S.

Attachment 1b (cont.)

Pursuant to s. 499.012(11)(b)4., F.S., to be certified as a designated representative, a person must receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and ss. 499.001-499.081 and the rules adopted by the department governing the wholesale distribution of prescription drugs.

Accordingly, and pursuant to the above referenced facts and law, the department hereby intends to suspend permit no. 23:01470 issued to Medline Industries, Inc. as an Out of State Prescription Drug Wholesaler because you have not complied with s. 499.012(11)(f), F.S. and otherwise do not have a designated certified representative on file with the Department that meets the requirements of Section 499.012 (11) F.S. which is a substantial failure to comply with ss. 499.001 – 499.081, F.S. and is a failure to meet the requirements for the permit, for which the suspension is authorized pursuant to Sections 499.067 (1) (a); 499.067 (1) (b) 2. F.S.

Therefore, the department concludes that Medline Industries, Inc. no longer meets the requirements to continue to operate as an Out of State Prescription Drug Wholesaler in Florida and the permit will be suspended until you have designated in writing to the department a person with an active certification to serve as a designated representative who meets the requirements of Section 499.012 (11) F.S.

NOTICE OF RIGHTS TO HEARING AND APPEAL

You have the right to request an administrative hearing pursuant to sections 120.569 and 120.57, F.S., if you wish to challenge the intended agency action to suspend your permit. Such proceedings are governed by sections 120.569 and 120.57, F.S., and Rules 28-106 and 28-107, Florida Administrative Code. Request for a hearing, formal or informal, must comply with Rule 28-107.004, Florida Administrative Code.

You have the right to be represented by counsel or other qualified representative, at your expense; to present evidence and argument; to call and cross-examine witnesses; and to have subpoena and subpoena duces tecum issued on your behalf if a hearing is requested.

A petition for administrative hearing must be in writing and must be received by the Agency Clerk for the Department, within twenty-one (21) days from the receipt of this complaint. The address of the Agency Clerk is 4052 Bald Cypress Way, BIN # A02, Tallahassee FL 32399-1703. The Agency Clerk's facsimile number is 850-410-1448.

Mediation is not available as an alternative remedy.

Your failure to submit a petition for hearing within 21 days from receipt of this complaint will constitute a waiver of your right to an administrative hearing, under Florida Administrative Code Rule 28-106.111 and this complaint shall become a "final order".

Attachment 1b (cont.)

Should this correspondence become a final order, a party who is adversely affected by it is entitled to judicial review pursuant to s 120.68, F.S. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings may be commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by the filing fees required by law, with the Court of Appeal in the appropriate District Court. The notice must be filed within 30 days of rendition of the final order.

Sincerely,

Rebecca R. Poston, R.Ph.
Executive Director
Drugs, Devices, & Cosmetics Program

RP/rb

Attachment 1c

Final Order No. DOH-08-0203-S-MQA
FILED DATE - 2-8-08
Department of Health
By: Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

Case No.: 2007-37412

vs.

MEDLINE INDUSTRIES, INC.,

Respondent.

FINAL ORDER

In this matter, the Florida Department of Health is proceeding under the Florida Drug and Cosmetics Act, Chapter 499, Florida Statutes. The Parties request a final order adopting their settlement agreement.

Being fully advised, the Parties' request is granted. On or about February 8, 2008, the Parties fully executed their "Settlement Agreement for Final Order", which is incorporated by reference. The "Settlement Agreement for Final Order" is approved, and the parties are directed to comply with it.

DONE and **ORDERED** this 8TH day of February 2008, in Tallahassee, Leon County, Florida.

ANA M. VIAMONTE ROS, M.D., M.P.H.
STATE SURGEON GENERAL

By: for
PAUL METTS, C.P.A., M.H.A.
DEPUTY SECRETARY

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been furnished via U.S. Mail, or fax delivery to: Edwin Bayo, Esq., Attorney for MEDLINE INDUSTRIES, INC., at Metzger, Grossman, Furlow & Bayo, L.L.C , 1408 North Piedmont Way, Tallahassee, Florida 32308, 850.385.4240 (facsimile) and via interoffice mail to Lynne A. Quimby-Pennock, Assistant General Counsel, Department of Health, 4052 Bald Cypress Way, Bin #C-65, Tallahassee, Florida 32399-3265 this 8 day of February 2008.

Deputy Agency Clerk
Department of Health
4052 Bald Cypress Way, Bin C-01
Tallahassee, Fl. 32399-3251

DELEGATION OF AUTHORITY
to
Deputy Secretaries and Chief of Staff

A. In accordance with the authority created in Sections 20.05(1)(a) and (b) and 20.43, Florida Statutes and vested in me as State Surgeon General for the Department of Health, the following authority is delegated:

1. Take all actions required for the effective direction and administration of the Department of Health in accordance with applicable Florida Statutes (F.S.), Florida Administrative Code (F.A.C.), and department policies.

2. In the absence of the State Surgeon General, each deputy is delegated authority to sign as the agency head or represent the State Surgeon General at any meetings within their respective areas, unless there is a specific delegation of authority.

3. In the absence of a deputy, the other deputies are delegated the authority to take all actions required for the effective administration and operation of that respective area, unless there is a specific delegation of authority.

4. Act as a hearing officer in proceedings required by Section 120.54(3)(c), F.S., (Hearings) and to enter any order in connection therewith.

5. Enter final orders in proceedings under Section 120.57, F.S. (Additional Procedures Applicable to Hearings).

6. Authorize policies and procedures within your respective areas; however, all department-wide policy and procedure changes that affect or have an impact on other areas such as statewide computer systems, standard audit practices, and workload for the Division of Administration, shall be coordinated with the appropriate division director. **The State Surgeon General approves and signs all department policies.**

7. Approve contracts (revenue and expenditure) and purchase orders $1 million or more. This authority may not be redelegated. **Exception: Fixed Capital Outlay contracts, change orders and additional FCO services authorizations are delegated to the Director of Administration, who may only redelegate to the Chief of General Services or Administrator of Design and Construction.**

8. Approve all grant applications and carryover requests greater than $250,000. Bureau of Revenue Management approval required for Central Office grant applications prior to submission to the awarding agency.

9. Approve the hiring of Senior Management Service and Selected Exempt Service employees at a bureau chief level or higher pursuant to Chapter 60L-33, F.A.C., and department policy.

10. Grant Career Service employees salary additives in excess of 10% in accordance with Rule 60L-32.0011, F.A.C., and department policy.

11. Grant employees an increase to base rate of pay in excess of 10%in accordance with Rule 60L-32.0011, F.A.C., and department policy.

12. Approve appointments of employees previously dismissed from the department or other state agency. Approve appointments of employees who resigned from the department or other state agency while under investigation; or pursuant to a settlement agreement; or in lieu of dismissal.

13. Approve exemptions under Section 435.07, F.S., for persons disqualified from employment under Section 435.04, F.S.

14. Issue decisions on collective bargaining grievances at Step 2, in accordance with the Florida Statutes, department policy, and the applicable collective bargaining agreement.

15. Authorize and approve out-of-state travel.

16. Approve Emergency Suspension Orders and Emergency Restriction Orders during the absence of the State Surgeon General.

17. Approve core contracts under Chapter 154, F.S., with the local Board of County Commissioners.

B. Exceptions to this authority, which require the approval of the State Surgeon General are:

1. All changes to organization structure, functions, and programs involving the moving of positions or units between budget entities and divisions, or any action requiring the Department of Management Services and the Governor's Office of Policy and Budget approval.

2. Appointment or dismissal of county health department directors/administrators, children's medical services medical directors, division directors, or office directors.

C. This authority may be modified for specified periods of time as desired by the State Surgeon General.

D. These delegations may not be redelegated without the approval of the State Surgeon General.

8/6/07
Effective Date

Ana Maria Viamonte Ros
Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General
Department of Health

STATE OF FLORIDA
FLORIDA DEPARTMENT OF HEALTH
Medline Industries, Inc.
Case #2007-37412

SETTLEMENT AGREEMENT FOR FINAL ORDER

IT IS AGREED and STIPULATED by and between the State of Florida, Department of Health and MEDLINE INDUSTRIES, INC., that:

1. The Department of Health, through its Division of Medical Quality Assurance, Drugs, Devices and Cosmetics Program, (referred to as "the Department", 4052 Bald Cypress Way, Bin C-04, Tallahassee, Florida 32399 is responsible for, among other duties, under the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes (the Act) and the rules adopted there under, Rule 64F12 Florida Administrative Code, the regulation and permitting of prescription drug manufacturing and wholesaling within and into Florida.

2. The Department has investigated MEDLINE INDUSTRIES, INC., (referred to as "Medline") which holds a prescription drug wholesale permit, permit number 22:1022, located at 2708 NE Waldo Road, Gainesville, Floirda32609-3323.

3. The Department investigated Medline during the week of November 26, 2007, and found Medline to be operating in violation of Chapter 499, Florida Statutes (F.S.). The specific violations alleged include:

a. s. 499.005(1), & (4) F.S., and 499.069(1), F.S. in violation of s. 499.0121(1) F.S., and Rule 64F-12.014(4) Florida Administrative Code (F.A.C.) - holding or offering for sale any drug, device or cosmetic that is adulterated or

misbranded or has otherwise been rendered unfit for human or animal use. Establishment to be maintained in a clean and orderly manner to prevent the product from becoming contaminated with filth or injurious to health. (The surplus warehouse was unclean with spiders, spider webs, dead insect bodies, bird feces/droppings and feathers therein.)

b. ss. 499.005(1) & (4), F.S., in accordance to s. 499.006(9), F.S., holding for sale adulterated medical devices on its inventory shelves through a failure to quarantine outdated medical devices.

c. ss. 499.005(4), 499.0121, F.S. & Rules 64F-12.013, & 64F-12.015(7)(a) F.A.C., - Improper Prescription drug storage, lack of climate control.

d. s. 499.0121(3), F.S. – Failure to notify the Department of all prescription drug sources.

e. s. 499.005(14), F.S. – Receiving prescription drugs from an unauthorized source.

f. ss. 499.005(18), 499.0121(6), F.S., and Rules 64F-12.012(5), 64F12.001(2), and 64F-12.012(3)(a), F.A.C., – failure to have pedigrees readily available for inspection.

g. s. 499.0121(7), F.S., inadequate SOP (standard operating procedures) or P&P (policy and procedures), or failing to follow them.

h. s. 499.005(24), F.S., distribution of legend devices to the ultimate user without a prescription or order from practitioner.

i. s. 499.005(4), F.S., in violation of s. 499.0121(2), F.S.,- unrestricted access to prescription drugs in that prescription drugs, devices and/or cosmetics are left on a loading dock for pick-up/delivery, but the area does not have restricted access.

4. On or about November 27 and/or 28, 2007, seizure orders were placed on numerous items in Medline's surplus warehouse and one pallet of product within the climate-controlled warehouse.

5. On January 22, 2008, an Order of Emergency Restriction of Permit was issued by State Surgeon General, Ana M. Viamonte Ros, M.D., M.P.H., restricting the specific use of the facility.

6. A Final Order in this case will incorporate the following agreed upon terms and conditions:

a. All items under the seizure order that contain prescription drug products shall be destroyed at Medline's expense at a Florida Chapter 499, F.S., permitted facility; all other seized items shall be destroyed by Medline at Medline's expense. Within ten (10) days of the destruction, Medline shall submit documentation detailing the destruction of said items to the Compliance Officer of the Florida Drug, Device and Cosmetic Program, at 4042 Bald Cypress Way, MQA/HSE, Tallahassee, Florida 32399.

b. All products remaining at Medline's facility that were received from J & L Medical, Inc., located at 784 Old Checker Ct.,

Buffalo Grove, Illinois, between June 2007 through November 27, 2007, shall be destroyed at Medline's expense at a Florida Chapter 499, F.S., permitted facility, or if the products do not contain prescription drugs shall be destroyed by Medline at Medline's expense. Within ten (10) days of the destruction, Medline shall submit documentation detailing the destruction to the Compliance Officer of the Florida Drug, Device and Cosmetic Program, at 4042 Bald Cypress Way, MQA/HSE, Tallahassee, Florida 32399.

c. Medline shall pay a fine of FIFTY THOUSAND DOLLARS ($50,000.00) to the Florida Drug, Device and Cosmetic Trust Fund. Said payment shall be by certified check, cashier check or money, and shall accompany this executed Settlement Agreement. Said check shall be made payable to the Florida Drug, Device and Cosmetic Trust Fund.

d. The Order of Emergency Restriction, entered by the Department on January 22, 2008, shall be lifted upon the filing of the Final Order adopting and accepting the terms of this Settlement Agreement.

e. Medline shall undergo quarterly inspections by the Department at Medline's expense for one (1) year from the issuance of the Final Order, to ensure proper compliance with Chapter 499, Florida Statutes and the rules thereto. The Department shall provide an invoice for the inspection that shall be paid within thirty (30) days of receipt by Medline. Said payment shall be sent to the Compliance Officer of the

Florida Drug, Device and Cosmetic Program, at 4042 Bald Cypress Way, MQA/HSE, Tallahassee, Florida 32399. The Department retains the authority to enter the permitted facility/warehouse at any time to conduct inspections/investigations as authorized by Florida law.

f. Medline shall conduct a training program, within thirty (30) days of the execution of this Settlement Agreement For Final Order, for its facility employees educating the employees on the requirements of Chapter 499, Florida Statutes and the applicable rules. Within ten (10) days of the training, Medline shall submit documentation detailing the training to the Compliance Officer of the Florida Drug, Device and Cosmetic Program, at 4042 Bald Cypress Way, MQA/HSE, Tallahassee, Florida 32399.

g. Medline shall comply with all applicable Federal and state law and rules, including but not limited to Chapter 499 Florida Statutes, and its applicable rules. Medline shall comply with all pedigree and audit trail requirements for all prescription drugs purchased, held and /or distributed by Medline, including the authentication of any prescription drugs received. Medline shall ensure that any automated pedigree system employed, shall satisfy the requirements of Chapter 499, F.S. and the applicable rules thereto.

h. Medline shall maintain its facility in a clean, orderly and pest/bird free environment.

7. By execution of this Settlement Agreement For Final Order and by the filing of the subsequent Final Order in this cause, the Department and Medline intend to and do resolve all issues pertaining to the above referenced investigation.

8. Medline neither admits nor denies the violations allege in the inspection/investigation reports generated by the Department's investigators in this cause.

9. Upon entry of the Final Order adopting this Agreement, the Department will not seek further disciplinary action against Medline based on any of the alleged violations described in the above listed case number. However, if there are future violations of Chapter 499, F.S., or the rules adopted thereto, the above listed case will be considered aggravating circumstances and will be construed as previous violations for purposes of assessing the amount of the fine to be levied pursuant to section 499.066(3)(c), F.S.

10. Medline voluntarily enters into this Settlement Agreement for Final Order and waives the right to a hearing in this matter and all further proceedings to which it may be entitled by law or administrative rules. Medline hereby knowingly and voluntarily waives all right to challenge or to contest this Settlement Agreement or the Final Order issued by the Department in any forum now or in the future available to them, including the right to any administrative proceeding,

circuit or federal court action, or any appeal. Both parties agree not to appeal this Settlement Agreement or the Final Order to be issued in this matter.

11. The signatories hereto represent that they have read this Agreement and are authorized to execute it on behalf of their respective principals and as duly designated representatives, to fully bind such principals, as well as the Parties successors and assigns. The terms of this Agreement are effective on the date of the last signature below. The original will be filed with a Final Order with the Department Clerk. Each signer will receive a copy of this Agreement.

12. This document is a public record and contains information that is routinely published by the Department. Upon the filing of this Agreement and entry of a Final Order by the Department the existence of the above reference case number and all matters therein are no longer confidential and exempt from public disclosure. All documents or records created or submitted for compliance issues shall be a public record when filed with the Department.

13. Each party to this proceeding shall bear its own costs and attorney fees.

14. The absences of a prohibition specifically listed in this Agreement shall not be construed as permission to engage in any activity that otherwise is in violation of section 499.001-499.081, Florida Statutes, or the rules promulgated thereunder.

15. Upon the filing of this Settlement Agreement for Final Order, the parties, as well as any person who may claim by or through them, hereby waive,

release and discharge the other, and any of their employees, attorneys, agents or representatives from all claims arising out of any act or omission related to the investigation and settlement of this matter. This release applies to any and all claims of any kind, whether known or unknowns and whether direct, indirect or derivative.

16. Upon execution of this Agreement the State Surgeon General or her designee will issue a Final Order incorporating the terms hereof.

17. The parties agree that should any legal dispute arise concerning enforcing the terms of this Agreement, venue shall be in Leon County, Florida and this Agreement shall be interpreted in accordance with applicable Florida law.

WHEREFORE the Parties request a final order adopting this Agreement as final agency action.

For: Medline Industries, Inc.,

Lara N Simmons February 7 2008
Lara N. Simmons
Corporate VP for QA and RA
Authorized Representative, Medline Industries, Inc.,

For the Department of Health - Drug, Device and Cosmetic Program
4052 Bald Cypress Way,
Tallahassee, Florida 32399, 850.245.4031 , 850.245.4682 Fax

Daisy Kurz for February 8 2008
Rebecca Poston, R.PH
Executive Director
Florida Drug, Device & Cosmetic Program
Department of Health

Attachment 1d

LOUISIANA BOARD OF
WHOLESALE DRUG DISTRIBUTORS

MEDLINE INDUSTRIES, INC. Covington, LA LICENSE NO. 4318	CONSENT ORDER ADMINISTRATIVE CASE NO. 2008006

In review of evidence presented to the Louisiana Board of Wholesale Drug Distributors (the "Board") addressing specific violation(s) of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors by MEDLINE INDUSTRIES, INC., Covington LA facility (the "Respondent", "Licensee"), acting herein by its authorized agent, to-wit: "Copies of current licenses for customers who are authorized by law or regulation to procure or possess drugs or devices shall be maintained for all customers that are shipped or sold drugs or devices. If customer licenses are maintained off site, a list of customer names, addresses, licenses numbers, and license expiration dates shall be maintained for all customers that are shipped or sold drugs or devices.", La. R.S. Title 37, Chapter 54, Section 3467, and LAC Title 46, Part XCI, Section 311.D and "violating provisions of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors", La. R.S. Title 37, Chapter 54, Section 3474.1 and LAC Title 46, Part XCI, Section 101.

Upon consideration of the evidence presented to the Board, this Consent Order is voluntarily entered into by and between Respondent and the Board. Respondent acting through its authorized agent, hereby waives formal Notice of and its attendance at the Evidentiary Hearing for presentation of the Consent Order to the Board. However, as a condition precedent to submission of the proposed Consent Order to the Board, Respondent hereby acknowledges and understands that information may be presented to the Board with regards to the details of the case for the Board to understand the circumstances. It is further acknowledged and understood by Respondent that in the event the Board is not agreeable to enter into the proposed Consent Order and an Administrative Hearing is ultimately conducted, the Board which will be presiding over the case will possibly have heard information which may later be submitted at the scheduled hearing. If such hearing occurs, Respondent waives any right that it may have to recuse or remove any or all members of the Board for the purposes of an Administrative Hearing in the event the proposed Consent Order is not accepted by the Board, or if Respondent withdraws his consent to the proposed Consent Order prior to its final approval by the Board. Furthermore, Respondent has had the opportunity to, or has in fact consulted with, legal counsel with regards to the Consent Order and the waivers contained herein.

FINDINGS OF FACTS

1. Respondent possesses Louisiana License No. 4318 issued by the Board to wholesale distribute legend drugs and devices in the State of Louisiana. Such license was in effect on 3/5/2008 through the date of the evidentiary hearing in this matter.

2. Pursuant to LAC 46:XCI.311.D, a licensee is required to maintain copies of current licenses for customer who are authorized by law or regulation to procure or possess legend drugs or devices for all customers that are shipped or sold legend drugs or devices; if these license copies are maintained off site, a list of customers with customer names, addresses, license number, and license expiration dates shall be maintained on site for all customers shipped or sold legend drugs or devices.
3. On 3/5/2008, an inspection was conducted by the Board's representative which revealed that copies of customer licenses were not at the Covington LA facility. A verbal request to provide a customer listing which should be maintained at the Covington LA facility was made. The customer license list was not available.
4. Information was thereafter submitted by Respondent to the Board's inspector as per the inspector's request. In review of a customer listing ("Pedigree List") as provided by the Respondent, the inspector requested copies of customer licenses for 15 of the customers listed. Verbal explanation was given was that customer licenses are verified and the customer is entered electronically into the system as an authorized recipient but that no hard copy of the customer license is being maintained.
5. Respondent's conduct in failing to maintain customer license documents and/or a customer listing at the Covington LA site is in violation of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors, specifically LAC 46:XCI.311.D.
6. Disciplinary sanctions and/or fines are applicable against Respondent in accordance with the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors.

CONCLUSIONS OF LAW

1. It is unlawful for Respondent, as a licensee to wholesale distribute legend drugs and devices, to not maintain current customer license documents and/or a current customer listing on-site. LAC 46:XCI.311.D.
2. It is unlawful for Respondent, as a licensee to wholesale distribute legend drugs and devices, to violate any of the provisions of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors. La. R.S. 37:3474.1 and LAC 46:XCI.101
3. Respondent's violations of the provisions of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors constitute lawful grounds for the Louisiana Board of Wholesale Drug Distributors, upon due notice of hearing and proof of such violations, to assess a fine, revoke, suspend, or otherwise discipline Respondent's license as provided by law. La. R.S. 37:3474.1 and LAC 46:XCI.701 et seq.

DECISION

4. Respondent is hereby assessed a fine in the amount of $2,000 for its failure to properly maintain copies of current licenses for customers shipped or sold legend drugs or devices and/or a customer listing on site. Said fine to be paid on the effective date of

this Consent Order. No practice restrictions are placed on Respondent's license issued by the Board.

5. The existence and terms of this Consent Order will not be confidential or privileged information in accordance with the laws regarding public records.
6. Respondent hereby releases the Board, its representative, and attorney from any obligations or liability in their endeavors to administer this Consent Order.
7. The effective date of this Consent Order shall be such date it is accepted by the Board.
8. Respondent, through its authorized agent, declares that, before signing this Consent Order, it has carefully read this document, and it knows and understands the contents thereof, it signs it as an act of it own free will, it understands its meaning and effect, it has been given the opportunity to consult with an attorney, it voluntarily waives all rights to formal notice and a formal public hearing, as well as its appearance at the proceedings, and it consents to this Consent Order.

THUS DONE AND PASSED, on the 1 date of May, 2008 at the City of Mundelein, Parish/County of Lake, Louisiana/ Illinois, in the presence of the two undersigned competent witnesses, who hereunto sign their names with Appearer and me, Notary, after due reading of the whole.

WITNESSES:

MEDLINE INDUSTRIES, INC.
Covington LA

Signature of Authorized Agent

Laura A. Simmons
Print Name of Authorized Agent

Notary Public

OFFICIAL SEAL
SUSAN MILLER
Notary Public - State of Illinois
My Commission Expires Jul 16, 2011

Attachment 1d (cont.)

LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS
12046 Justice Avenue, Suite C
Baton Rouge, LA 70816
(225) 295-8567 Fax (225) 295-8568 lsbwdd@bellsouth.net www.lsbwdd.org

April 28, 2008

Lara N. Simmons, VP-QA/RA
MEDLINE INDUSTRIES, INC.
One Medline Place
Mundelein, IL 60060

RE: Louisiana License No. 4318
Administrative Docket No. 2008006

CERTIFIED MAIL
No. 7007 3020 0000 4431 9031
Return Receipt Requested

Dear Lara Simmons:

As you may recall, the Board is mandated by law to license and regulate the wholesale distribution of legend drugs and devices in Louisiana in accordance with the Louisiana Revised Statutes and Louisiana Administrative Codes for wholesale drug distributors. This letter will acknowledge receipt of your response dated 4/3/2008. This letter is also intended to respond to any inquiries you may have regarding the deficiencies found during the inspection which occurred on 3/5/2008 at MEDLINE INDUSTRIES, INC.'s Covington LA distribution facility.

Pursuant to the Louisiana Revised Statutes and Louisiana Administrative Codes, specifically LAC 46:XCI.311.D, a licensee should maintain copies of current licenses which authorizes a customer to procure and possess legend drugs and devices. If these customer licenses are maintained off site, a list of customers including customer names, addresses, license number, and the license expiration dates shall be maintained for all customers that are shipped or sold drugs or devices.

On 3/5/2008, the Board's inspector discovered that copies of customer licenses which authorize the customer to procure and possess legend drugs/devices or a listing of customers' license information were not being maintained at the Covington LA facility.

A verbal request was made by the inspector of a customer list which should have been maintained at the Covington LA facility. After receiving and reviewing a copy of the customer list, as referred to by Medline as their "Pedigree List", the inspector requested copies of 30 customer licenses from the listing. Of the requested customer license copies, the inspector found that 70% of the licenses requested were either not acceptable licenses or were not available.

It is evident that MEDLINE INDUSTRIES, INC. was in violation of LAC 46:XCI.311.D at the time of the inspection on 3/5/2008. The Louisiana Revised Statutes and Louisiana Administrative Codes for wholesale drug distributors, more particularly LA RS 37:3474.1, provides that, after due notice and hearing, MEDLINE INDUSTRIES, INC.'s license may be sanctioned and/or it may be assessed a fine for its actions or omissions. Fines alone may include an assessment of $1,000 per violation

Bob Brandao, Chairman | William Crates, Vice-Chairman | Randall Brooks, Secretary/Treasurer | John Liggio, Executive Director/Inspector
Hershel Paul, Board Member | Andy Mulligan, Board Member | Wayne Gremillion, Board Member | Eric Vidrine, Board Member | Kathleen B. Barpes, Executive Assistant

Attachment 1d (cont.)

per day. It is the Board's objective to regulate the industry by correcting behavior. Such is accomplished by imposing sanctions for wrongful conduct.

It is hoped that the above detailed violation(s) as corrected will not occur in the future. Therefore, in an effort to amicably resolve the issues regarding the violation(s) which did occur, I, as the Board's appointed investigating/compliance officer, extend an offer to you which would impose a total fine of $2,000. This proposed sanction does not impose any restrictions on MEDLINE INDUSTRIES, INC.'s license.

If MEDLINE INDUSTRIES, INC. is agreeable to these terms, I have enclosed a Consent Order for your review and execution. Please have an authorized representative for your company sign the Consent Order in front of a Notary and two witnesses. Return the original, executed Consent Order along with a check made to the Louisiana Board of Wholesale Drug Distributors in the amount of the $2,000 fine to the Board's office within fifteen (15) days of receipt of this letter. You and/or a company representative will not be required to attend the evidentiary hearing at which the executed Consent Order will be presented to the full Board for acceptance, however you and/or another representative are welcome to attend.

In the event MEDLINE INDUSTRIES, INC. is not agreeable to this amicable resolution and wishes to contest the investigative findings in a hearing before the full Board, it has the right to do so. If such occurs, the current offer being proposed in this letter will no longer be viable.

We would like to bring this matter to disposition either by this amicable resolution or the pursuit of a formal hearing against MEDLINE INDUSTRIES, INC. before the Board at the next scheduled Board meeting. To do so, either way, we will need to prepare the necessary paperwork with all resolution documents. Again, please respond to this offer either by returning the executed Consent Order and fine payment or by written request for an administrative hearing. If your response is not received at the Board office within fifteen (15) days of receipt of this letter, the Board will begin steps towards the formal hearing with the issuance of subpoenas for witnesses and records.

We wish to keep an open line of communication with you. Please contact the Board office in the event you have any questions. Thank you for your cooperation in this matter.

Respectfully,

Wayne Gremillion
Board Member/Compliance Officer

kbb
Encl: Consent Order
File
Cc: J Gregg/ T Stoecker, Covington LA

Attachment 1e

LINDA LINGLE
GOVERNOR

JAMES R. AIONA, JR.
LT. GOVERNOR

LAWRENCE M. REIFURTH
DIRECTOR
DEPARTMENT OF COMMERCE AND
CONSUMER AFFAIRS

JO ANN M. UCHIDA
COMPLAINTS AND
ENFORCEMENT OFFICER

STATE OF HAWAII
REGULATED INDUSTRIES COMPLAINTS OFFICE
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
LEIOPAPA A KAMEHAMEHA BUILDING
235 SOUTH BERETANIA STREET, NINTH FLOOR
HONOLULU, HAWAII 96813
FAX: (808) 586-2670
TELEPHONE: (808) 586-2660

HILO OFFICE
345 KEKUANAOA STREET, SUITE 12
HILO, HAWAII 96720

KONA OFFICE
KEAUHOU SHOPPING CENTER, ROOM
134A
78-6831 ALII DRIVE
KAILUA-KONA, HAWAII 96740

MAUI OFFICE
1063 LOWER MAIN STREET, SUITE C-216
WAILUKU, HAWAII 96793

KAUAI OFFICE
3060 EIWA STREET, ROOM 204
LIHUE, HAWAII 96766

July 8, 2008

Ms. Dianna J. Wolfe
Regulatory Affairs Specialist
Medline Industries, Inc.
One Medline Place
Mundelein, Illinois 60060

Re: RICO Case No. PHA 2008-71-L

Dear Ms. Wolfe:

I received the signed Settlement Agreement. One correction had to be made, and I apologize that we did not notice this earlier. On page 3, paragraph 5, the citation to HRS section 436B-19(13) was changed to HRS section 436B-19(15) which is the correct citation. Enclosed is a copy of the corrected replacement page. I will now forward the document to the executive officer of the Board of Pharmacy, and we will be notified as to whether it gets approved or not by the Board.

Very truly yours,

Bobbi Lum-Mew

Bobbi W.Y. Lum-Mew
Staff Attorney

/BLM
Enclosure

Attachment 6b.

DARIA A. LOY-GOTO 6175
BOBBI W.Y. LUM-MEW 6299
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorney for Department of Commerce
and Consumer Affairs

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Wholesale Prescription Drug Distributor's License of	)	PHA 2008-17-L
MEDLINE INDUSTRIES INC.,	)	SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHBITS "1" THROUGH "5"
Respondent.	)	

241092407

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorneys, and Respondent MEDLINE INDUSTRIES INC. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS

1. At all relevant times herein, Respondent was licensed by the Board of Pharmacy (hereinafter the "Board") as a wholesale prescription drug distributor under License Number

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

PWD 115. The license was issued on or about October 3, 2005. The license will expire on or about December 31, 2009.

2. Respondent's mailing address for purposes of this action is One Medline Place, Mundelein, Illinois 60060.

3. RICO received information that disciplinary action had been taken against Respondent's licenses by the States of Missouri and Florida. Specifically, RICO received information regarding the following:

a). Respondent entered into a Settlement Agreement with the Missouri State Board of Pharmacy. Pursuant to the terms of a Joint Agreed Disciplinary Order, Respondent's Missouri drug distributor's license was placed on probation and Respondent was ordered to comply with certain terms and conditions. A true and correct copy of the Settlement Agreement and Joint Agreed Disciplinary Order dated July 19, 2005 in Settlement Agreement Between State Board of Pharmacy and Medline Industries, Inc., is attached as Exhibit "1";

b). Respondent was issued a Letter of Warning and Notice of Serious Violations by the Missouri State Board of Pharmacy. A true and correct copy of the Letter of Warning and Notice of Serious Violations dated February 15, 2007 regarding Medline Industries, Inc., is attached as Exhibit "2";

c). Respondent was issued an Order of Emergency Suspension of Permit by the State of Florida's Department of Health. Pursuant to the terms of the Order, Respondent's Florida prescription drug wholesaler's permit was immediately suspended . A true and correct copy of the Order of Emergency Suspension of Permit by the State of Florida's Department of Health dated January 14, 2008 in In Re: Emergency Suspension of the Permit of Medline Industries, Inc., is attached as Exhibit "3";

d). Respondent was issued an Order of Emergency Restriction of Permit by the State of Florida's Department of Health. Pursuant to the terms of the Order, Respondent's Florida prescription drug wholesaler's permit was immediately restricted. A true and correct copy of the Order of Emergency Restriction of Permit by the State of Florida's Department of Health dated January 22, 2008 in In Re: Emergency Restriction of the Permit of Medline Industries, Inc., is attached as Exhibit "4";

e). Respondent entered into a Settlement Agreement with the State of Florida's Department of Health. Pursuant to the terms of a Final Order, Respondent was, among other things, ordered to undergo quarterly inspections and pay a $50,000.00 fine. A true and correct copy of the Settlement Agreement for Final Order dated February 8, 2008 in Settlement Agreement for Final Order regarding Medline Industries, Inc., is attached as Exhibit "5."

4. RICO alleges that although Respondent reported the actions on a December 5, 2007 renewal application, Respondent failed to report the disciplinary actions within thirty (30) days as required by Hawaii law.

5. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(15) (failure to report disciplinary action within thirty days) and § 436B-19(17) (violating applicable laws or rules).

6. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein licensed as a wholesale prescription drug distributor by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the license and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's license.

6. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

7. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2008-17-L.

C. TERMS OF SETTLEMENT:

1. Probation. Respondent's wholesale prescription drug distributor's license is hereby placed on probation for a period of five (5) years. During the probationary period, Respondent agrees to comply with the following terms of the probation as set forth in paragraphs C.2, C.3, and C.4 below:

2. Comply with Terms of Missouri Probation. Respondent shall comply with the terms of its probation in the July 19, 2005 Settlement Agreement Between State Board of Pharmacy and Medline Industries, Inc.. During the probationary period, Respondent shall report to the Hawaii Board of Pharmacy, in writing, any additional action by the State of Missouri within ten (10) days of such action. During the probationary period, Respondent shall deliver to the Hawaii Board proof of Respondent's compliance with the Missouri Settlement Agreement.

3. Comply with Terms of Florida Final Order. Respondent shall comply with the terms of the February 8, 2008 Settlement Agreement for Final Order. During the probationary period, Respondent shall report to the Hawaii Board of Pharmacy, in writing, any additional action by the State of Florida within ten (10) days of such action. During the probationary period, Respondent shall deliver to the Hawaii Board proof of Respondent's compliance with the Florida Settlement Agreement.

4. Administrative fine. Respondent agrees to pay a fine in the amount of FIVE THOUSAND AND NO/100 DOLLARS ($5,000.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: Bobbi Lum-Mew, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this fully executed Settlement Agreement is returned to RICO.

5. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1, C.2, C.3 and C.4 above, Respondent's license shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the license to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new license until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become licensed again, Respondent must apply to the Board for a new license pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

6. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of wholesale prescription drug distributors in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

7. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.8, C.9, C.10 and C.11 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

8. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

9. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

10. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any

representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

11. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: _____, _____, _____.

MEDLINE INDUSTRIES INC.

By: _____
Its _____

DATED: Honolulu, Hawaii, JUL 0 8 2008.

Bobbi W.Y. Lum-Mew

DARIA A. LOY-GOTO
BOBBI W.Y. LUM-MEW
Attorneys for Department of Commerce and Consumer Affairs

IN THE MATTER OF THE WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR'S LICENSE OF MEDLINE INDUSTRIES INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; PHA 2008-17-L; EXHBITS "1" THROUGH "5"

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

ELWIN D.H. GOO
Chairperson

DATE

MARK E. BROWN
Vice-Chairperson

LAURIE H. Y. KAWAMURA

KENT KIKUCHI

KARL H. MIYAMOTO

PATRICK ADAMS

STANLEY M. CHOW

PVL 09/05/07

STATE OF Illinois)
) SS.
COUNTY OF Lake)

On this 5 day of July, 2007, before me personally appeared Lisa Sowers, to me known to be the person described, and who executed the foregoing instrument on behalf of Medline Industries as Corporate VP of Sales, and acknowledged that he/she executed the same as his/her free act and deed.

OFFICIAL SEAL
SUSAN MILLER
Notary Public - State of Illinois
My Commission Expires Jul 16, 2011

Name:
Notary Public, State of

My Commission expires: 7-16-2011

Attachment 1f

Final Order No. DOH-08-2129-S-MQA
FILED DATE - 9-19-08
Department of Health
By: [signature]
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

Case No.: 2007-11783; 2007-36555; 2007-38894; 2007-38895; 2007-38896; 2007-39073; 2008-02011; 2008-11215

vs.

MEDLINE, INDUSTRIES, INC.,

Respondent.
_____/

FINAL ORDER

A Notice of Violation letter was sent to the Respondent by the Department on May 14, 2008. Having received an Offer of Settlement, which is attached hereto as Exhibit A, this matter is before the Department of Health for the entry of a final order.

The Offer of Settlement was executed on or about September 19, 2008 and submitted together with the payment.

The Offer of Settlement is accepted and incorporated by reference. The parties are directed to comply with the terms of the Agreement.

It is, therefore, *ORDERED* that this matter and proceeding be *CLOSED*.

DONE and **ORDERED** this 26 day of September 2008, in Tallahassee, Leon County, Florida.

ANA M. VIAMONTE ROS, M.D., M.P.H.
State Surgeon General

By: Rebecca R. Poston
Rebecca R. Poston, R.Ph.
Executive Director
Drugs, Devices and Cosmetics

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been furnished via U.S. mail to: **Edwin Bayo, Esq., Attorney for MEDLINE INDUSTRIES, INC., at Metzger, Grossman, Furlow & Bayo, L.L.C., 1408 North Piedmont Way, Tallahassee, Florida 32308**, this 29 day of September, 2008.

Deputy Clerk

cc: Lynne Quimby-Pennock, DOH 4052 Bald Cypress Way, Bin #C-65 Tallahassee, FL 32399
Richard Sands, DOH 4052 Bald Cypress Way, Bin #C-70

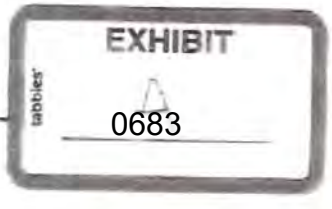
SETTLEMENT AGREEMENT

Medline Industries, Inc., Case No.: 2007-11783, Permit No.: 22:596; Case No.: 2007-36555, Permit No.: No valid permit since 12.21.2006; Case No. 2007-38894, Permit No. 20:168; Case No. 2007-38895, Permit No.: 21:166; Case No. 2007-38896, Permit No.: 07:545; Case No.: 2007-39073, Permit No.: None; Case No. 2008-02011, Permit No.: None; Case No. 2008-11215, Medline Manufacturing & Services, LLC Permit No.: None

Pursuant to Section 120.57(4), Florida Statutes (2007), the above named parties hereby enter into this global stipulation as disposition of the attached administrative action, in lieu of any other administrative proceedings authorized in Chapter 120, Florida Statutes. The terms herein become effective upon rendition of the final order which shall incorporate the Settlement Agreement.

STIPULATED FACTS

1) Medline Industries Inc., and Medline Manufacturing & Services, LLC, (hereinafter collectively known as "Medline") neither admit nor deny the alleged violations in the attached Notice of Violation.
2) During the time the alleged violations occurred, Medline held certain Florida permits including: Permit No.: 22:596, a prescription drug wholesaler; Permit No.:20:168, a prescription drug manufacturer; Permit No.: 21:166 an Over the Counter Manufacturer; and Permit No.: 07:545 a device manufacturer within the state of Florida; however Medline is alleged to have failed to have certain other permits in the Notice of Violation.
3) The Department is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 20.43, Florida Statutes (2007), and Chapter 499, Florida Statutes (2007).



CONCLUSIONS OF LAW

4) Medline, by and through its undersigned agent, admits that it is subject to the provisions of Chapter 499, Florida Statutes (2007), and the jurisdiction of the Department.

5) Medline admits that the findings set forth in the Notice of Violation, if proven, would constitute violations of Chapter 499, Florida Statutes (2007).

6) Medline agrees that the Department's acceptance of the Settlement Agreement constitutes disciplinary action within the meaning of Section 499.066, Florida Statutes (2007), and Rule 64F-12.024, Florida Administrative Code.

SETTLEMENT

7) Medline agrees to pay a fine of ONE HUNDRED FIFTY THOUSAND DOLLARS ($150,000.00), and acknowledges that payment, made payable to the Florida Drug, Device and Cosmetic Trust Fund, is enclosed with this agreement.

8.) Medline affirms the violations cited the Notice of Violation letter issued under these case numbers have been corrected or are being corrected immediately. Medline shall provide written documentation of the return of the seized products to a licensed reverse distributor within thirty (30) days of the execution of this agreement. The documentation shall be sent to the Florida Drug Device and Cosmetic Program Office, Department of Health, 4052 Bald Cypress Way, Bin C04, Tallahassee, FL 32399-3255. Upon receipt of documentation demonstrating the return of the seized products, the seizure order shall automatically be lifted.

9) Medline affirms that it shall comply with all provisions of the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes, and the rules adopted thereunder.

10) It is expressly understood that a violation of the terms of this Settlement Agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary actions may be taken.

11) Medline expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Settlement Agreement incorporated in the Final Order.

12) Medline waives the right to seek any attorney's fees or costs from the Department in connection with this disciplinary proceeding.

Corporate Seal:

By: _____ 9/19/08
President (or authorized agent) Date

Attested by: _____ _____
Corporate Secretary Date

By: Rebecca R Poston 9/26/08
Authorized DOH Representative Date

Attachment 1g

Jim Doyle
Governor

Celia M. Jackson
Secretary

WISCONSIN DEPARTMENT OF REGULATION & LICENSING

1400 E Washington Ave
PO Box 8935
Madison WI 53708-8935
Email: web@drl.state.wi.us
Voice: 608-266-2112
FAX: 608-266-2264
TTY: 608-267-2416

November 18, 2008

Jan Hornick
Medline Industries Inc.
5450 W. Stewart Ave.
Wausau, WI 54401

Re: 08 PHM 037

Dear Ms. Hornick:

As you know, an inspector for the Department of Regulation and Licensing inspected Medline Industries on May 9, 2008. He found that several policies were missing, and the facility was storing prescription drugs in a non-secure location. It has been determined that these violations are grounds for discipline. I am the prosecuting attorney assigned to the case.

I have enclosed a proposed stipulation and order, which would resolve this matter without a hearing. If you are willing to resolve this case by agreement, please sign and return the stipulation and order by **December 9, 2008**. I will then present it to the Pharmacy Examining Board at its next meeting. The stipulation and order is not binding unless and until it is accepted by the board.

If you do not return the signed stipulation and order by December 9, 2008, I will file a formal complaint and initiate the hearing process. Please be aware that it is the policy of the Department to assess costs against respondents whenever any discipline is imposed. Your costs are presently $100. If we have to take this matter through a hearing, they will escalate quickly and could reach several thousand dollars.

Please call if you have any questions.

Sincerely,

Jeanette Lytle
Attorney
Division of Enforcement
608-266-9840

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
MEDLINE INDUSTRIES INC. RESPONDENT.	:	STIPULATION LS# _____

Division of Enforcement Case # 08 PHM 037

Respondent Medline Industries Inc., by its manager Jan Hornick; and Jeanette Lytle, attorney for the Department of Regulation and Licensing, Division of Enforcement, stipulate:

1. This Stipulation is entered into as a result of a pending investigation of Respondent's licensure by the Division of Enforcement (case # 08 PHM 037). Jan Hornick represents, by her signature below, that she has authority to enter into this agreement on behalf of Respondent. Ms. Hornick, on behalf of Respondent, consents to the resolution of this investigation by stipulation.

2. Respondent's manager, Jan Hornick, understands that by signing this Stipulation she voluntarily and knowingly waives on behalf of Respondent its rights, including: the right to a hearing on the allegations against it, at which time the state has the burden of proving those allegations by a preponderance of the evidence; the right to confront and cross-examine witnesses; the right to call witnesses and to compel their attendance by subpoena; the right to testify; the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision; the right to petition for rehearing; and all other applicable rights afforded to it under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and any other provisions of state or federal law.

3. Respondent has been provided an opportunity to obtain the advice of legal counsel prior to signing this stipulation.

4. Jan Hornick agrees, on behalf of Respondent, to the adoption of the attached Final Decision and Order by the Pharmacy Examining Board. The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall be returned to the Division of Enforcement for further proceedings. In the event that this Stipulation is

not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by consideration of this attempted resolution.

6. The parties to this Stipulation agree that the attorney or other agent for the Division of Enforcement and any member of the Pharmacy Examining Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of the Respondent or its attorney, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with the Board's deliberations on the Stipulation. Additionally, any such Board advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's final decision and order is a public record and will be published in accordance with standard Department procedure.

8. The Division of Enforcement joins Jan Hornick in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.

Medline Industries Inc.

By: Jan Hornick _____ 11-24-08

Jan Hornick, manager
5450 West Stewart Avenue
Wausau, WI 54401

Date

_____ _____

Jeanette Lytle
Attorney
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935
Madison, WI 53708-8935

Date

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
MEDLINE INDUSTRIES INC., RESPONDENT.	:	LS # _____

Division of Enforcement Case # 08 PHM 037

The parties to this action for the purposes of Wis. Stat. § 227.53 are:

Medline Industries Inc.
5450 W. Stewart Ave.
Wausau, WI 54401

Division of Enforcement
Department of Regulation and Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

Pharmacy Examining Board
Department of Regulation & Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

PROCEDURAL HISTORY

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Pharmacy Examining Board. The Board has reviewed the attached Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. Medline Industries Inc. is duly licensed as a wholesale distributor of prescription drugs in Wisconsin (license # 45-1116). This license was first granted on June 21, 1999.

2. Respondent's most recent address on file with the Wisconsin Pharmacy Examining Board is 5450 W. Stewart Avenue, Wausau, Wisconsin 54401.

3. The Department of Regulation and Licensing conducted an unannounced inspection on May 9, 2008. The following violations were noted:

(a) The following policies were missing: Recall policy [Wis. Admin. Code § Phar 13.15(2)], Emergency plan [Wis. Admin. Code § Phar 13.15(3)], Outdated stock policy [Wis. Admin. Code § Phar 13.15(4).

(b) Respondent was storing Complete Delivery Systems (pre-packaged kits for surgeries, including various types and quantities of prescription drugs) in a warehouse it shared with another company. The CDS kits were not secured and employees of the other company had unhindered access to the kits, in violation of Wis. Admin. Code § Phar 13.10(3).

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter, pursuant to Wis. Stat. §450.10, and is authorized to enter into the attached Stipulation and Order, pursuant to Wis. Stat. § 227.44(5).

2. The conduct described in paragraph 3 above constitutes a violation of Wisconsin Administrative Code § Phar 13.10(3), Phar 13.15(2), (3) and (4), and Wis. Stat. § 450.10(1)(a)2 and 6 and subjects Respondent to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

ORDER

IT IS ORDERED:

1. Medline Industries Inc. is REPRIMANDED.

2. Respondent shall, within ninety (90) days from the date of this Order, pay a FORFEITURE in the amount of Two Thousand Dollars ($2,000.00).

3. Respondent shall, within ninety (90) days from the date of this Order, pay costs of this proceeding in the amount of One Hundred Dollars ($ 100.00). Payment shall be made payable to the Wisconsin Department of Regulation and Licensing, and mailed to:

Department Monitor
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935

Madison, WI 53708-8935
Telephone (608) 267-3817
Fax (608) 266-2264

4. In the event Respondent fails to pay the forfeiture as ordered, or in the event it fails to pay costs as ordered, Respondent's license (#45-1116) SHALL BE SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of this Order.

5. This Order is effective on the date of its signing.

Dated this __ day of _____, 2008.

PHARMACY EXAMINING BOARD

By: _____
A Member of the Board

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
MEDLINE INDUSTRIES INC., RESPONDENT.	:	LS # 0902046PHM

Division of Enforcement Case # 08 PHM 037

The parties to this action for the purposes of Wis. Stat. § 227.53 are:

Medline Industries Inc.
5450 W. Stewart Ave.
Wausau, WI 54401

Division of Enforcement
Department of Regulation and Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

Pharmacy Examining Board
Department of Regulation & Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

PROCEDURAL HISTORY

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Pharmacy Examining Board. The Board has reviewed the attached Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. Medline Industries Inc. is duly licensed as a wholesale distributor of prescription drugs in Wisconsin (license # 45-1116). This license was first granted on June 21, 1999.

2. Respondent's most recent address on file with the Wisconsin Pharmacy Examining Board is 5450 W. Stewart Avenue, Wausau, Wisconsin 54401.

3. The Department of Regulation and Licensing conducted an unannounced inspection on May 9, 2008. The following violations were noted:

(a) The following policies were missing: Recall policy [Wis. Admin. Code § Phar 13.15(2)], Emergency plan [Wis. Admin. Code § Phar 13.15(3)], Outdated stock policy [Wis. Admin. Code § Phar 13.15(4).

(b) Respondent was storing Complete Delivery Systems (pre-packaged kits for surgeries, including various types and quantities of prescription drugs) in a warehouse it shared with another company. The CDS kits were not secured and employees of the other company had unhindered access to the kits, in violation of Wis. Admin. Code § Phar 13.10(3).

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter, pursuant to Wis. Stat. §450.10, and is authorized to enter into the attached Stipulation and Order, pursuant to Wis. Stat. § 227.44(5).

2. The conduct described in paragraph 3 above constitutes a violation of Wisconsin Administrative Code § Phar 13.10(3), Phar 13.15(2), (3) and (4), and Wis. Stat. § 450.10(1)(a)2 and 6 and subjects Respondent to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

ORDER

IT IS ORDERED:

1. Medline Industries Inc. is REPRIMANDED.

2. Respondent shall, within ninety (90) days from the date of this Order, pay a FORFEITURE in the amount of Two Thousand Dollars ($2,000.00).

3. Respondent shall, within ninety (90) days from the date of this Order, pay costs of this proceeding in the amount of One Hundred Dollars ($ 100.00). Payment shall be made payable to the Wisconsin Department of Regulation and Licensing, and mailed to:

Department Monitor
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935

Madison, WI 53708-8935
Telephone (608) 267-3817
Fax (608) 266-2264

4. In the event Respondent fails to pay the forfeiture as ordered, or in the event it fails to pay costs as ordered, Respondent's license (#45-1116) SHALL BE SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of this Order.

5. This Order is effective on the date of its signing.

Dated this 1 day of February, 2009.

PHARMACY EXAMINING BOARD

By: _____
A Member of the Board

BOBBI W.Y. LUM-MEW 6299
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorney for Department of Commerce
and Consumer Affairs

2009 MAY 22 A 9:24

2009 MAY 29 A 9:4

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Wholesale Prescription Drug Distributor's License of	)	PHA 2009-7-L
MEDLINE INDUSTRIES INC.,	)	SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"
Respondent.	)	

241092407

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorneys, and Respondent MEDLINE INDUSTRIES INC. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS

1. At all relevant times herein, Respondent was licensed by the Board of Pharmacy (hereinafter the "Board") as a wholesale prescription drug distributor under License Number PWD 115. The license was issued on or about October 3, 2005. The license will expire on or about December 31, 2009.

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

2. Respondent's mailing address for purposes of this action is Dianna Wolfe, Corporate Regulatory Affairs Specialist, Medline Industries, Inc., One Medline Place, Mundelein, Illinois 60060.

3. Respondent timely reported that disciplinary action had been taken against Respondent by the State of Wisconsin. Respondent had entered into a Stipulation with the State of Wisconsin's Pharmacy Examining Board. Pursuant to the terms of a Final Order, Respondent was reprimanded and ordered to pay a forfeiture in the amount of $2,000.00. This action was based on the results of an inspection which revealed that certain policies were missing and that Respondent was storing pre-packaged kits for surgeries (which included various types and quantities of prescription drugs) in a warehouse that was shared with another company. These kits were not secured and employees of the other company had access to the kits. A true and correct copy of the Stipulation and Final Decision and Order which was approved on February 4, 2009 is attached as Exhibit "1."

4. RICO alleges that Respondent was disciplined by another state for a reason provided by the licensing laws in Hawaii. Specifically, the Respondent was disciplined for professional misconduct.

5. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(13) (disciplinary action by another state) and § 461-21(a)(2) (professional misconduct). Per Hawaii Administrative Rules §§ 16-95-30(c)(6) and (9), a licensee's facility must be secure from unauthorized entry and entry into areas where prescription drugs are held must be limited to authorized personnel.

6. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein licensed as a wholesale prescription drug distributor by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the license and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's license.

6. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

7. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2009-7-L.

C. TERMS OF SETTLEMENT:

1. Administrative fine. Respondent agrees to pay a fine in the amount of ONE THOUSAND AND NO/100 DOLLARS ($1,000.00). Payment shall be made by **cashier's check, company check, or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: Bobbi Lum-Mew, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due within thirty (30) days after this Settlement Agreement is approved by the Board.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph C.1 above, Respondent's license shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the license to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new license until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become licensed again, Respondent must apply to the Board for a new license pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of wholesale prescription drug distributors in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5, C.6, C.7 and C.8 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: Mundelein, IL, 5/11/09.
(CITY) (STATE) (DATE)

MEDLINE INDUSTRIES INC.

By: [signature]
Its Pres. of GAIRA

DATED: Honolulu, Hawaii, MAY 19 2009.

[signature]
DARIA A. LOY-GOTO
BOBBI W.Y. LUM-MEW
Attorneys for Department of Commerce and Consumer Affairs

IN THE MATTER OF THE WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR'S LICENSE OF MEDLINE INDUSTRIES INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; PHA 2009-7-L; EXHIBIT "1"

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

ELWIN D.H. GOO
Chairperson

June 18, 2009
DATE

MARK E. BROWN
Vice-Chairperson

LAURIE H. Y. KAWAMURA

KENT KIKUCHI

KARL H. MIYAMOTO

PATRICK ADAMS

STANLEY M. CHOW

PVL 05/20/08

STATE OF Illinois)
) SS.
COUNTY OF Lake)

On this 11 day of May, 2009, before me personally appeared Lacy V Simms, to me known to be the person described, and who executed the foregoing instrument on behalf of Medline Industries as President, CEO/CFO, and acknowledged that he/she executed the same as his/her free act and deed.

OFFICIAL SEAL
SUSAN MILLER
Notary Public - State of Illinois
My Commission Expires Jul 16, 2011

Name: Susan Miller
Notary Public, State of IL

My Commission expires: July 16, 2011

2009

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
MEDLINE INDUSTRIES INC., RESPONDENT.	:	LS # 0902046PHM

Division of Enforcement Case # 08 PHM 037

The parties to this action for the purposes of Wis. Stat. § 227.53 are:

Medline Industries Inc.
5450 W. Stewart Ave.
Wausau, WI 54401

Division of Enforcement
Department of Regulation and Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

Pharmacy Examining Board
Department of Regulation & Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

PROCEDURAL HISTORY

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Pharmacy Examining Board. The Board has reviewed the attached Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. Medline Industries Inc. is duly licensed as a wholesale distributor of prescription drugs in Wisconsin (license # 45-1116). This license was first granted on June 21, 1999.

EXHIBIT "1"

2. Respondent's most recent address on file with the Wisconsin Pharmacy Examining Board is 5450 W. Stewart Avenue, Wausau, Wisconsin 54401.

3. The Department of Regulation and Licensing conducted an unannounced inspection on May 9, 2008. The following violations were noted:

(a) The following policies were missing: Recall policy [Wis. Admin. Code § Phar 13.15(2)], Emergency plan [Wis. Admin. Code § Phar 13.15(3)], Outdated stock policy [Wis. Admin. Code § Phar 13.15(4).

(b) Respondent was storing Complete Delivery Systems (pre-packaged kits for surgeries, including various types and quantities of prescription drugs) in a warehouse it shared with another company. The CDS kits were not secured and employees of the other company had unhindered access to the kits, in violation of Wis. Admin. Code § Phar 13.10(3).

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter, pursuant to Wis. Stat. §450.10, and is authorized to enter into the attached Stipulation and Order, pursuant to Wis. Stat. § 227.44(5).

2. The conduct described in paragraph 3 above constitutes a violation of Wisconsin Administrative Code § Phar 13.10(3), Phar 13.15(2), (3) and (4), and Wis. Stat. § 450.10(1)(a)2 and 6 and subjects Respondent to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

ORDER

IT IS ORDERED:

1. Mediine Industries Inc. is REPRIMANDED.

2. Respondent shall, within ninety (90) days from the date of this Order, pay a FORFEITURE in the amount of Two Thousand Dollars ($2,000.00).

3. Respondent shall, within ninety (90) days from the date of this Order, pay costs of this proceeding in the amount of One Hundred Dollars ($ 100.00). Payment shall be made payable to the Wisconsin Department of Regulation and Licensing, and mailed to:

Department Monitor
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935

Madison, WI 53708-8935
Telephone (608) 267-3817
Fax (608) 266-2264

4. In the event Respondent fails to pay the forfeiture as ordered, or in the event it fails to pay costs as ordered, Respondent's license (#45-1116) SHALL BE SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of this Order.

5. This Order is effective on the date of its signing.

Dated this 4 day of February, 2009.

PHARMACY EXAMINING BOARD

By: _____
A Member of the Board

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF :
DISCIPLINARY PROCEEDINGS AGAINST :
:
MEDLINE INDUSTRIES INC. :
RESPONDENT. :

STIPULATION
LS#0902046PHM

Division of Enforcement Case # 08 PHM 037

Respondent Medline Industries Inc., by its manager Jan Hornick; and Jeanette Lytle, attorney for the Department of Regulation and Licensing, Division of Enforcement, stipulate:

1. This Stipulation is entered into as a result of a pending investigation of Respondent's licensure by the Division of Enforcement (case # 08 PHM 037). Jan Hornick represents, by her signature below, that she has authority to enter into this agreement on behalf of Respondent. Ms. Hornick, on behalf of Respondent, consents to the resolution of this investigation by stipulation.

2. Respondent's manager, Jan Hornick, understands that by signing this Stipulation she voluntarily and knowingly waives on behalf of Respondent its rights, including: the right to a hearing on the allegations against it, at which time the state has the burden of proving those allegations by a preponderance of the evidence; the right to confront and cross-examine witnesses; the right to call witnesses and to compel their attendance by subpoena; the right to testify; the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision; the right to petition for rehearing; and all other applicable rights afforded to it under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and any other provisions of state or federal law.

3. Respondent has been provided an opportunity to obtain the advice of legal counsel prior to signing this stipulation.

4. Jan Hornick agrees, on behalf of Respondent, to the adoption of the attached Final Decision and Order by the Pharmacy Examining Board. The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall be returned to the Division of Enforcement for further proceedings. In the event that this Stipulation is

not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by consideration of this attempted resolution.

6. The parties to this Stipulation agree that the attorney or other agent for the Division of Enforcement and any member of the Pharmacy Examining Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of the Respondent or its attorney, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with the Board's deliberations on the Stipulation. Additionally, any such Board advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's final decision and order is a public record and will be published in accordance with standard Department procedure.

8. The Division of Enforcement joins Jan Hornick in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.

Medline Industries Inc.

By: Jan Hornick 11-24-08

Jan Hornick, manager
5450 West Stewart Avenue
Wausau, WI 54401

Date

12/10/08

Jeanette Lytle
Attorney
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935
Madison, WI 53708-8935

Date

Attachment 1i

Dora
Department of Regulatory Agencies

Division of Registrations
Rosemary McCool
Director

State Board of Pharmacy
Wendy Anderson
Program Director

Bill Ritter, Jr.
Governor

Barbara J. Kelley
Executive
Director

March 24, 2010

MedLine Industries, Inc.
Attn: Scott C. Barbour, Designated Representative
1401 N. Universal Ave.
Kansas City, MO 64120

RE: Stipulation and Final Agency Order
Case #2010-2994

IN THE MATTER OF DISCIPLINARY RPOCEEDINS REGARDING THE LICENSE TO PRACTICE AS A OUT-OF-STATE WHOLESALER IN THE STATE OF COLORADO OF MEDLINE INDUSTRIES, INC.,

Dear Mr. Barbour:

Enclosed you will find a copy of the fully executed Stipulation and Final Agency Order (Stip/FAO) in the above mentioned matter, which became effective March 19, 2010.

Accordingly, and pursuant to Conditional Registration, item 9, of the Stip/FAO, MedLine Industries, Inc., at the above listed location, has been issuec out-of-state prescription drug wholesaler registration #7713, with conditions, effective March 23, 2010.

Medline Industries, Inc., Colorado out-of-state wholesaler registration #7713 shall be probationary pending the Colorado State Board of Pharmacy's receipt of a request for discharge from Medline Industries, Inc., which must include documentation showing Medline Industries, Inc.'s release from the terms and conditions of the Missouri Settlement Agreement effective 8/3/05.

If you have any questions, or require additional information, please feel free to contact me at (303) 894-2989.

Respectfully,

FOR THE COLORADO STATE BOARD OF PHARMACY

Tia Johnson
Complaint Analyst
Enclosure
cc: Beth Thompson, Vice President, Regulatory Affairs, Medline Industries, Inc.
John Steele, Settlement Specialist, Office of Expedited Settlement
Jazell Carter, Licensing Specialist, Office of Licensing
File

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2010-002994

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE LICENSE TO PRACTICE AS A OUT-OF-STATE WHOLESALER IN THE STATE OF COLORADO OF MEDLINE INDUSTRIES, INC.,

Wholesaler Applicant.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Medline Industries, Inc. ("Wholesaler Applicant") to resolve all matters pertaining to Board Case Number 2010-002994 as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Wholesaler Applicant, its application for registration as an out-of-state wholesaler and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S.

2. Wholesaler Applicant admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

3. Wholesaler Applicant entered into a Settlement Agreement with the Missouri State Board of Pharmacy, which was effective on August 3, 2005 ("Missouri Settlement Agreement").

4. In the Missouri Settlement Agreement, Wholesaler Applicant was placed on probation for five (5) years for various violations of Missouri state and federal law involving recordkeeping, storage of prescription drugs, change of location without informing the Missouri Board of Pharmacy, lack of a policy and procedure manual, and distribution of prescription drugs under a lapsed registration.

5. Wholesaler Applicant's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes:

12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(III) Any state or federal law pertaining to drugs.

12-22-125.2. Disciplinary actions.

(1) The board may deny or discipline an applicant, licensee, or registrant when the board determines that such applicant, licensee, or registrant has engaged in activities that are grounds for discipline.

6. On January 14, 2010, Wholesaler Applicant submitted an out-of-state wholesaler application, which application was denied by the Board.

7. On March 1, 2010, Wholesaler Applicant submitted a written request asking that the Board accept its application by granting a conditional license.

8. The Board finds and concludes, and Wholesaler Applicant agrees, that based upon Wholesaler Applicant's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances as a condition of its registration as an out-of-state wholesaler.

DISPOSITION

Conditional Registration / Probation / Compliance / Terms

9. **Conditional Registration.** Wholesaler Applicant shall be granted a registration as an out-of-state wholesaler upon execution of this Final Agency Order and satisfaction of the terms and conditions set forth herein.

10. **Probation.** Wholesaler Applicant's registration shall be placed on probation for a period of time equal to the time of probation remaining under the Missouri Settlement Agreement. Credit toward satisfying the period of probation under this Final Agency Order shall be given only during such periods of time that Respondent is in total compliance with all provisions of this Final Agency Order and the Missouri Settlement Agreement.

11. **Compliance.** Wholesaler Applicant shall at all times remain in compliance with §§12-22-801, *et seq.* C.R.S. and shall not at any time distribute prescription drugs into Colorado without being registered as an out-of-state wholesaler in the State of Colorado at the time of distribution.

12. **Other Requirements.** Wholesaler Applicant acknowledges and agrees that, as a condition of this Final Agency Order and probation, Wholesaler Applicant shall:

    a. promptly pay all Wholesaler Applicant's own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

13. **Discharge.** Discharge from the requirements of this Final Agency Order must be requested in writing by Wholesaler Applicant. The Board will consider any request for discharge during the ordinary course of business. In any request for discharge it shall be Wholesaler Applicant's sole responsibility to establish, through written and other documentation, that Wholesaler Applicant has met all terms and conditions of this Final Agency Order and, in addition, has been released from probation by the Missouri Board of Pharmacy under the Missouri Settlement Agreement. Wholesaler Applicant's probation under this Final Agency Order shall continue until formally discharged by the Board by way of Board order.

14. **Advisements and Waivers.** Wholesaler Applicant enters into this Final Agency Order freely and voluntarily, whether or not Wholesaler Applicant has consulted with legal counsel. Wholesaler Applicant acknowledges its understanding that it has the following rights:

    a. To have a formal notice of hearing and charges served upon it;
    b. To respond to said formal notice of charges;
    c. To have a formal disciplinary hearing pursuant to §12-22-125, C.R.S.; and
    d. To appeal this Board order.

    Wholesaler Applicant freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

15. **Acknowledgments.** The undersigned authorized agent of Wholesaler Applicant has read this Final Agency Order in its entirety and acknowledges, whether or not Wholesaler Applicant has consulted with legal counsel, that Wholesaler Applicant

understands the legal consequences and agrees that none of the terms or conditions herein are unconscionable.

16. **Violations.** Time is of the essence to this Final Agency Order. It is the responsibility of Wholesaler Applicant to take all appropriate steps to comply fully with this Final Agency Order. Wholesaler Applicant acknowledges and agrees that any violation of this Final Agency Order may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Wholesaler Applicant to comply with all terms and conditions of this Final Agency Order.

17. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

18. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

19. **Effective Date.** This Final Agency Order shall become effective upon signature of a Board member or representative.

ACCEPTED AND AGREED BY

Dated: 3/12/10

Authorized Agent of Wholesaler Applicant

Subscribed and sworn to by Lisa N. Simmons, in his/her capacity as an authorized agent of Medline Industries, Inc., before me in the County of Lake, State of Illinois, this 12 day of March, 2010.

OFFICIAL SEAL
SUSAN MILLER
Notary Public - State of Illinois
My Commission Expires Jul 16, 2011

Notary Public

My commission expires: 7-16-2011

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 19th day of January, 2010.

State Board of Pharmacy

BY: Wendy Anderson

Wendy Anderson
Program Director

CERTIFICATE OF MAILING

This is to certify that I have duly mailed the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 5th day of March 2010, addressed as follows:

Medline Industries, Inc.
Attn: Scott C. Barbour, Designated Representative
1401 N. Universal Ave.
Kansas City, MO 64120

Beth Thompson
Vice President, Regulatory Affairs
Medline Industries, Inc.
1 Medline Pl.
Mundelein, IL 60060

John Steele
John C. Steele

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 24th day of March 2010, addressed as follows:

Medline Industries, Inc.
Attn: Scott C. Barbour, Designated Representative
1401 N. Universal Ave.
Kansas City, MO 64120

Beth Thompson
Vice President, Regulatory Affairs
Medline Industries, Inc.
1 Medline Pl.
Mundelein, IL 60060

Eric Johnson
Agent of the Board

Dora
Department of Regulatory Agencies

Division of Registrations
Rosemary McCool
Director

State Board of Pharmacy
Wendy Anderson
Program Director

Bill Ritter, Jr.
Governor

Barbara J. Kelley
Executive
Director

August 25, 2010

MedLine Industries, Inc.
Attn: Scott C. Barbour, Designated Representative
1401 N. Universal Ave.
Kansas City, MO 64120

RE: Stipulation and Final Agency Order (Stip/FAO), effective 3/19/10
Case #2010-2994

Dear Mr. Barbour:

Staff for the Colorado State Board of Pharmacy ("Board") has reviewed the material concerning Medline Industries' request for release from the terms and conditions of the above listed Stip/FAO effective 3/19/10.

After due consideration, and pursuant to Board Policy 10-6, staff for the Board released Medline Industries, Inc., from the terms and conditions of the 3/19/10 Stip/FAO, and restored its out-of-state prescription drug wholesaler registration #7713 to unencumbered status, effective 8/25/10.

Your cooperation during the pendency of this matter is sincerely appreciated.

Sincerely,

FOR THE COLORADO STATE BOARD OF PHARMACY

Wendy L. Anderson
Program Director

cc: Beth Thompson, Vice President, Regulatory Affairs, Medline Industries, Inc.
File

Policy Number: 10-6

Title: Delegation of Authority to Program Director or Section Director

Date Issued: 11/16/2006

Dates Revised: 8/21/08, 10/16/08, 9/17/09, 1/21/10, 7/15/2010

PURPOSE: To clarify the authority which has been delegated to the Program Director, Section Director, or his/her designee

POLICY: The Board of Pharmacy has delegated to the Program Director, Section Director or his/her designee the authority to:

1. Sign Stipulations and Final Agency Orders ("Stipulations") and final orders issued subsequent to initial decisions entered after hearings held by administrative law judges ("Final Board Orders") on its behalf.
2. Issue Final Board Orders on its behalf when no exceptions are filed to the initial decision, the statutorily allowed time frame for the filing of exceptions has passed, the recommended sanction from the Administrative Law Judge is the same as that sought by the Board, and no further decisions are required by the Board.
3. Process reports of settlement of malpractice claims in the same manner as signed complaints are handled.
4. Accept, on the Board's behalf, practice and treatment monitoring reports and any other such reports submitted as required by the Stipulation or Final Board Order, provided such reports are in compliance with the terms of the Stipulation or Final Board Order.
5. Initiate complaints and issue 30-day letters to licensees or registrants currently under Stipulation or Final Board Order if, in the opinion of the Program Director or his/her designee, the licensee or registrant has failed to comply with any of the terms of his or her stipulation.
6. Sign Suspension Orders as required by the Child Support Enforcement Program.
7. Subpoena documents and gather information in order to assist the Board in carrying out its duties.
8. Approve practice monitors for licensees and registrants as required pursuant to Stipulations or Final Board Orders.
9. Sign suspension orders on its behalf.
10. Sign cease and desist orders on its behalf.
11. Perform the initial review of complaints relating to the practice of licensees or registrants under the Board's jurisdiction and to issue 30-day letters relating to the complaints.
12. Initiate complaints and issue 30-day letters where otherwise authorized by the Board.
13. Determine non-substantive procedural matters relating to the rendering of initial decisions, including, but not limited to, granting extensions of time for the filing of exceptions, and granting requests for oral argument.
14. Perform additional delegated duties as set forth in Board policies.

15. Make referrals for assessment to the Pharmacy Peer Assistance Diversion Program.

16. Suspend the licenses of individuals under Stipulation or Final Board Order if licensee is required to participate in the Pharmacy Peer Assistance Diversion Program as a requirement of his/her Stipulation or Final Board Order and fails to comply with his/her contract with the Rehabilitation Evaluation Committee. The Program Director or his/her designee may lift the Board suspension on such licenses when the licensee has resumed compliance.

17. Release licensees and registrants from the terms of their Stipulations or Final Board Orders provided the licensee submits satisfactory evidence of completion of all terms of the Stipulation or Final Board Order. The Program Director or his/her designee, at his/her discretion, may refer any request for discharge to the Board for review.

18. Deny requests from licensees and registrants for discharge from the terms of Stipulations or Final Board Orders when the licensee or registrant has not completed the terms of the Stipulation or Final Board Order. Requests for early discharge from Stipulations and Final Board Orders shall be denied.

19. Suspend the licenses or registrations of facilities which have been ordered to pay a fine pursuant to a Stipulation or Final Board Order and fail to remit the required payment. In the event the licensee or registrant is to pay the fine in installments, the Program Director or his/her designee may suspend the license or registration if the licensee or registrant fails to remit a required payment. The Program Director or his/her designee may lift the Board suspension on such licenses or registrations when the licensee or registrant has come into compliance with fine requirements.

20. Enter, on its behalf, written agreements with public or private entities whereby the Board may provide information from the Electronic Prescription Drug Monitoring Program that does not identify a patient, prescriber, or dispenser of a prescription drug. Such agreements may only be entered into for the purposes of bona fide research or education pursuant to CRS 12-22-705(5).

21. Notice, on its behalf, proposed rules or proposed amendments or deletions to rules for a hearing before the board pursuant to CRS 24-4-103.

22. In the absence of additional exculpatory evidence or information not previously before the board, reject any counteroffer from respondents with cases at the Office of Expedited Settlement that is not within the board's settlement parameters.

23. Issue on its behalf, the "Board Procedural Order regarding Review of Initial Decision" upon receipt of an Initial Decision from an Administrative Law Judge at the Office of Administrative Courts.

Attachment 1j

THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK

OFFICE OF PROFESSIONAL DISCIPLINE
(212) 921-3872/3873

1411 BROADWAY – TENTH FLOOR
NEW YORK, NEW YORK 10018

July 18, 2014

Medline Industries Inc., Pharmacy Wholesaler
3301 Route 6
Middletown, NY 10940

Re: License No. 028250

Dear Sir or Madam:

Enclosed please find Order No. 27278. This letter will explain when the Order regarding the above respondent goes into effect.

If the penalty imposed by the Order is an annulment, revocation, surrender, or an actual suspension (suspension which is not wholly stayed) of your license, you must deliver your license and registration to this Department within ten (10) days after the date of this letter.

In the event you are personally served with the Order, the Order is effective as of the date of the personal service. In the event you are served by certified mail and are not personally served with the Order, the Order is effective five (5) days after the date of this letter. The Order will take effect as indicated in this letter, even if you fail to meet the time requirement of delivering your license and registration to this Department.

If the penalty imposed by the Order is a revocation or a surrender of your license, you may, pursuant to Rule 24.7 (b) of the Rules of the Board of Regents, a copy of which is attached, apply for restoration of your license after three years have elapsed from the effective date of the Order and the penalty. Please be advised that said application is not granted automatically.

The record and reports of a disciplinary proceeding or resulting voluntary settlement shall be considered matters of public information unless specifically excepted by law or applicable rule or regulation.

Very truly yours,

DONALD DAWSON
Director of Investigations
By: Ariana Miller
ARIANA MILLER
Supervisor

LJC/AM/nbm
Enclosure
CERTIFIED MAIL – RRR
cc: Judith A. Eisen, Esq.
Garfunkel Wild, P.C.
111 Great Neck Road
Great Neck, NY 11021

VOTE AND ORDER

MEDLINE INDUSTRIES INC.

CALENDAR NO. 27278

NEW YORK STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE
STATE BOARD OF PHARMACY
----------X

IN THE MATTER

of the

Disciplinary Proceeding

against

MEDLINE INDUSTRIES INC.

which is currently registered to operate as a pharmacy wholesaler in the State of New York.
----------X

APPLICATION FOR CONSENT ORDER

CAL. NO. 27278

LARA N. SIMMONS states:

That I am President, Quality Assurance and Regulatory Affairs of **MEDLINE INDUSTRIES INC.**, hereinafter referred to as the Respondent, and make this application on Respondent's behalf.

That on or about February 21, 2007 Respondent was registered to operate as a pharmacy wholesaler in the State of New York, having been issued Registration No. 028250 by the New York State Education Department.

Respondent is currently registered with the New York State Education Department to operate as a pharmacy wholesaler in the State of New York from an address at: 3301 Route 6, Middletown, New York 10940.

Respondent has been charged with one (1) specification of professional misconduct, a copy of which is annexed hereto, made a part hereof, and marked as Exhibit "A". Respondent admits

MEDLINE INDUSTRIES INC.

guilt to the aforesaid specification of professional misconduct, charging it with having been found guilty of improper professional practice or professional misconduct by a duly authorized professional disciplinary agency of another state where the conduct upon which the finding was based would, if committed in New York State, constitute professional misconduct under the laws of New York State (findings of misconduct committed during the period 2008 to 2009 by three separate states which, if committed in New York, would constitute professional misconduct under the Education Law and Commissioner's Regulations).

Respondent hereby agrees to the penalty that it pay a fine in the amount of five thousand dollars ($5,000.00), said fine to be paid by certified or cashier's check, made payable to the order of the New York State Education Department, to be delivered to the Director, Office of Professional Discipline, 1411 Broadway, 10th Floor, New York, New York 10018-3496, within thirty (30) days after the effective date of the Order to be issued in this matter.

Respondent hereby makes this application to the Board of Regents and requests that it be granted.

Respondent understands that in the event that the Board of Regents denies the application, nothing contained herein shall be binding upon it or construed to be an admission of any act of misconduct alleged or charged against it. Such application shall

not be used against it in any way and shall be kept in strict confidence during the pendency of the disciplinary proceeding, and such denial by the Board of Regents shall be without prejudice to the continuance of the disciplinary proceeding and the final determination by the Board of Regents pursuant to the provisions of the Education Law.

Respondent agrees that in the event the Board of Regents grants its application, as set forth herein, an Order may be issued in accordance with the same. Respondent understands that if and when the Board of Regents grants this application, the entire application shall become a matter of public record.

No promises of any kind were made to Respondent. Respondent is making this application of its own free will and accord and not under duress, compulsion, or restraint of any kind or manner.

LARA N. SIMMONS

EXHIBIT "A"

MEDLINE INDUSTRIES INC.

SPECIFICATION OF PROFESSIONAL MISCONDUCT

Respondent is charged with having been found guilty of improper professional practice or professional misconduct by a duly authorized professional disciplinary agency of another state where the conduct upon which the finding was based would, if committed in New York State, constitute professional misconduct under the laws of New York State, within the purview and meaning of New York Education Law section 6509(5)(b), in that:

(a) On or about September 26, 2008, the Department of Health of the State of Florida, a duly authorized disciplinary agency of said state, issued a Final Order against the Respondent (Case No. 2007-11783);

(b) The conduct upon which said Final Order was based was that (1) Respondent failed to provide in a timely manner documents that were requested and (2) Respondent sold or transferred a legend drug to a person who was not authorized under the law of the jurisdiction in which the person received the drug to purchase or possess legend drugs from the Respondent;

(c) Said conduct, if committed in New York, would constitute professional misconduct under Section 6509(13) of the Education Law and Part 63.6(c)(5)

of the Commissioner's Regulations;

(d) On or about May 1, 2008, the Louisiana Board of Wholesale Drug Distributors, a duly authorized disciplinary agency of Louisiana, issued a Consent Order against the Respondent (Administrative Case No. 2008006);

(e) The conduct upon which said Consent Order was based was that Respondent failed to maintain current customer license documents and/or a current customer listing on-site;

(f) Said conduct, if committed in New York, would constitute professional misconduct under Part 63.6(c)(5) of the Commissioner's Regulations;

(g) On or about February 4, 2009, the Wisconsin Pharmacy Examining Board, a duly authorized disciplinary agency of Wisconsin, issued a Final Decision and Order (Case #08-PHM 037);

(h) The conduct upon which said Decision and Order was based was that when Respondent was inspected by the Wisconsin Department of Regulation and Licensing, it was found that certain policies were missing and that it was storing prescription drugs in a warehouse it shared with another company;

(i) Said conduct, if committed in New York, would constitute professional misconduct under Part 63.6(c)(4) of the Commissioner's Regulations and

Title 21, Section 205.50, Code of Federal Regulations (CFR).

NEW YORK STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE
STATE BOARD OF PHARMACY

----------X

IN THE MATTER

of the

Disciplinary Proceeding

against

MEDLINE INDUSTRIES INC.

which is currently registered to operate as a pharmacy wholesaler in the State of New York.

----------X

APPLICATION FOR CONSENT ORDER

CAL. NO. 27278

The undersigned agree to the above statement and to the proposed penalty based on the terms and conditions thereof.

MEDLINE INDUSTRIES INC.

Dated: 2/14, 2014

Respondent

BY:

Lara N. Simmons, President, Quality Assurance and Regulatory Affairs

Dated: 2/18, 2014

Attorney for Respondent

Dated: 2/27, 2014

Member, State Board of Pharmacy

Dated: 3/6, 2014

Executive Secretary
State Board of Pharmacy

Dated: 4/23, 2014

Director
Office of Professional Discipline

The undersigned, a member of the Board of Regents who has been designated by the Chairman of the Regents Committee on Professional Practice to review this Application for a Consent Order, has reviewed said Application and recommends to the Board of Regents that the Application be granted.

Dated: 5/2, 2014

Member, Board of Regents

:ds

Section 24.7 (b) For individuals served prior to June 20, 1997 with an order of revocation, acceptance of surrender, or denial of an application for restoration or reinstatement by vote of the Board of Regents, at least one year shall have elapsed from the date of such service for the acceptance by the department of a petition to the Board of Regents for restoration of a license or certificate, except that a period of time during which the license was suspended during the pendency of the discipline proceeding may reduce the one-year waiting period. For individuals served on or after June 20, 1997 with an with an order of revocation, acceptance of surrender, or denial of an application for restoration or reinstatement by vote of the Board of Regents, at least three years shall have elapsed from the date of such service for the acceptance by the department of a petition to the Board of Regents for restoration of a license or certificate, except that a period of time during which the license was suspended during the pendency of the discipline proceeding may reduce the three-year waiting period. This section shall not apply to restoration of licenses which have been temporarily surrendered pursuant to Education Law, section 6510-b, or Public Health Law, section 230(13).

Attachment 1k

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE No. A-2020-0054
I-2019-0972-B

Medline Industries, Inc.
c/o Willis Ingalls
1501 Harris Road
Libertyville, IL 60048

License No. 01-1985050

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Medline Industries, Inc. for the purpose of resolving all issues between the parties relating to the Board investigation of a selling dangerous drugs to an unlicensed entity. Together, the Board and Medline Industries are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Medline Industries, LLC, has an active WDDD license with the Board under license number 01-1985050, which lists Willis Ingalls as the Responsible Person.

FACTS

1. The Board initiated an investigation of Medline Industries, WDDD license number 01-1985050, related to the sale of dangerous drugs to an unlicensed entity.

2. On or about December 3, 2020, the Board sent a Notice of Opportunity for Hearing to Medline Industries, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Medline Industries neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated December 3, 2020, however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Medline Industries agrees to pay to the Board a monetary penalty the amount of $250.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. Medline Industries agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. Medline Industries agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Medline Industries of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Medline Industries by the Board and will NOT discharge Medline Industries from any obligation under the terms of this Agreement.

6. Medline Industries agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. Medline Industries understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Medline Industries will operate.

9. Medline Industries expressly waives its opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Willis A. Ingalls — 1-5-21

Willis Ingalls, on behalf of,
Medline Industries, Respondent

Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

Jennifer McRudell, RPh. — 1-6-2021

Jennifer M. Rudell, RPh, President,
State of Ohio Board of Pharmacy

Date of Signature

1-6-2021

Henry Appel, Ohio Assistant Attorney General

Date of Signature

Attachment 1I

Alabama Board of Pharmacy
111 Village Street
Birmingham AL 35242

USPS CERTIFIED MAIL



9414 8118 9876 5809 1318 98

MEDLINE INDUSTRIES, INC.
1501 HARRIS ROAD
LIBERTYVILLE IL 60048



$5.86 US POSTAGE
FIRST-CLASS
Jun 28 2021
Mailed from ZIP 35242
1 oz First-Class Mail Letter

11923275



062S0012913542

FO - 21-L-0048 193718

DocuSign Envelope ID: 7F8AA924-F79F-4BC6-A7E1-B16F9D238852

THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	
MEDLINE INDUSTRIES, INC.	)	BOARD OF PHARMACY
	)	
Wholesale Distributor Permit No. 193718	)	CASE NO: 21-L-0048

FINAL ORDER

On June 15, 2021, this cause came before the Alabama State Board of Pharmacy (hereinafter also referred to as the "Board"), on a Complaint against Medline Industries, Inc. (hereinafter also referred to as the "Respondent"). Evidence having been adduced thereon, the Board has determined that the following Findings of Fact and Conclusions of Law are supported by the preponderant weight of evidence and law.

Findings of Fact

1. The Respondent is a wholesale distributor permitted by this Board under Permit No. 193718. (Board Exhibit One)

2. The Respondent was properly notified of the charges on March 9, 2021. The Respondent did not appear at the scheduled hearing before the Board and was not represented by counsel at such hearing. (Board Exhibit One and Two)

3. The Respondent made no objection to the timeliness of the Notice of Hearing or the specificity of the Statement of Charges.

4. The Respondent violated Board Rules 680-X-2.23, 680-X-2.23(3), 680-X-2.23(3)(k)(1), 680-X-2.23(3)(k)(2), and 680-X-2.23(3)(k)(3) and Code of Alabama (1975), § 34-23-32 based upon Respondent's underlying conduct in its entry into a Settlement Agreement with the State of Ohio Board of Pharmacy dated January 6, 2021 (Attached) in which discipline was

DocuSign Envelope ID: 7F8AA924-F79F-4BC6-A7E1-B16F9D238852

imposed. In that Settlement Agreement, Respondent admitted that the State of Ohio Board of Pharmacy had evidence sufficient to sustain the allegations that Respondent made five (5) illegal sales of dangerous drugs to Columbus Podiatry & Surgery, Inc.

Conclusions of Law

1. The Alabama State Board of Pharmacy has jurisdiction of this cause pursuant to Code of Alabama (1975), § 34-23-,32 Code of Alabama (1975), § 34-23-92(12), and Code of Alabama (1975), § 41-22-12.

2. The Respondent was properly notified of the charges, failed to appear and was not represented by counsel at the administrative hearing. The Respondent did not contest the matter in any manner.

3. The Respondent made no objection to the timeliness of the Notice of Hearing or the specificity of the Statement of Charges.

4. The Respondent is due to be fined $500.00 in that it is guilty of violating Board Rules 680-X-2.23, 680-X-2.23(3), 680-X-2.23(3)(k)(1), 680-X-2.23(3)(k)(2), and 680-X-2.23(3)(k)(3) and Code of Alabama (1975), § 34-23-32 in regard to its conduct involving illegal sales of dangerous drugs which resulted in discipline/Settlement Agreement dated January 6, 2021 with the State of Ohio Board of Pharmacy.

ORDER

In accordance with the foregoing Findings of Fact and Conclusions of Law, it is hereby ORDERED as follows:

DocuSign Envelope ID: 7F8AA924-F79F-4BC6-A7E1-B16F9D238852

1. The Respondent is guilty as charged in Count One as contained in the Statement of Charges and Notice of Hearing and is hereby fined a total of Five Hundred ($500.00) Dollars.

2. The disciplinary fine of Five Hundred ($500.00) Dollars is due and payable to the Board within thirty (30) days of the date of this Final Order.

DONE and ORDERED, this 28th day of June, 2021.

Brenda R. Denson, Pharm.D., President
Alabama State Board of Pharmacy

Copies to:
Medline Industries, Inc.
Ms. Donna C. Yeatman, R. Ph., Executive Secretary
Mr. James S. Ward, Esq.
Mr. James F. Hampton, Esq.
Mr. Vance L. Alexander, Esq.

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. A-2022-0333
I-2022-0624

Medline Industries, LP
c/o James Eveland
1040 Enterprise Parkway South
West Jefferson, OH 43162

License No. 01-30000190

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Medline Industries, LP, for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of dangerous drugs to an unlicensed entity. Together, the Board and Medline Industries, LP are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Medline Industries, LP, is a licensed Distributor of Dangerous Drug, License No. 01-30000190, which lists James Eveland, as the Responsible Person.

FACTS

1. The Board initiated an investigation of Medline Industries, LP, Distributor of Dangerous Drugs License No. 01-30000190, related to Medline Industries, LP's illegal sales of dangerous drugs to an unlicensed entity.

2. On or about September 28, 2022, the Board sent a Notice of Opportunity for Hearing to Medline Industries, LP, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Medline Industries, LP neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated September 28, 2022; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Medline Industries, LP agrees to pay to the Board a monetary penalty in the amount of $1,125.00. This fine will be attached to your license record and must be paid no later than 180 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. The Board hereby imposes a written reprimand on Medline Industries, LP's WDDD license, number 01-30000190.

5. Medline Industries, LP agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

6. Medline Industries, LP agrees to comply with all federal and state requirements related to Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Medline Industries, LP of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Medline Industries, LP by the Board and will NOT discharge Medline Industries, LP from any obligation under the terms of this Agreement.

7. Medline Industries, LP agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. Medline Industries, LP understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Medline Industries, LP will operate.

10. Medline Industries, LP waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

14. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

15. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

James J. Eveland

James Eveland, on behalf of,
Medline Industries, LP, Respondent

10-25-2022
Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

Shawn C Wilt

Shawn Wilt, RPh, President,
State of Ohio Board of Pharmacy

11.1.2022
Date of Signature

FILED
Department of Business and Professional Regulation
Senior Deputy Agency Clerk
CLERK: Brandon Nichols
Date: 12/21/2022
File #: 2022-09829

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner,

v. **Case No.: 2022-031132**

MEDLINE INDUSTRIES, LP,

Respondent,

_____/

FINAL ORDER

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics ("the Department"), in accordance with the provisions of Section 120.57(4), Florida Statutes, hereby enters this Final Order incorporating and adopting, *in toto*, the Settlement Agreement entered into between Medline Industries, LP, and the Department, attached hereto and incorporated by reference.

This Final Order is effective on the date it is filed with the Agency Clerk of the Department as indicated on this Final Order.

DONE and ORDERED this 19th day of December, 2022 in Tallahassee, Florida.

MELANIE S. GRIFFIN, SECRETARY

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

By: _____

Walter S. Copeland, Director
Division of Drugs, Devices, and Cosmetics

Prepared by:

Anthony Coniglio
DDC Chief Attorney

NOTICE OF RIGHT TO APPEAL

Unless expressly waived, any party adversely affected by this Final Order may seek judicial review by filing an original Notice of Appeal with the Clerk of the Department of Business & Professional Regulation, and a copy of the Notice, accompanied by the filing fees prescribed by law, with the clerk of the appropriate District Court of Appeal within 30 days of the effective date of this order, in accordance with Florida Rule of Appellate Procedure 9.110, and Section 120.68, Florida Statutes.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of this Final Order has been provided by regular US mail to: Corporation Service Company, Registered Agent for Medline Industries, LP, 1201 Hays Street, Tallahassee, Florida 32301 on this 21st day of December, 2022.

By: Brandon M. Nichols
Agency Clerk's Office

RECEIVED
[illegible] 09 2022
DRUGS, DEVICES AND COSMETICS

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner, **Case No.: 2022-031132**

v.

MEDLINE INDUSTRIES, LP,

Respondent.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the above-named parties hereby enter into this Settlement Agreement (hereinafter, "this agreement") as disposition of the alleged violations described in the Notice of Violation in case number 2022-031132 (hereinafter, "the allegations"). The terms herein become effective upon rendition of the final order, which shall incorporate this agreement.

The State of Florida, Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (hereinafter, "the Department") is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 20.165 and Chapter 499, Florida Statutes.

STIPULATED FACTS

1. Medline Industries, LP (hereinafter, "Respondent") is permitted by the Department as a prescription drug wholesale distributor, having been issued permit number 22:20297.

2. Respondent's address of record is 9670 Northwest 112th Avenue, Miami, Florida 33178.

3. Respondent was issued a Notice of Violation on October 26, 2022, alleging that it committed certain violations of Chapter 499, Florida Statutes, and the administrative rules adopted

pursuant thereto.

CONCLUSIONS OF LAW

4. Respondent, by and through its undersigned agent, admits that it is subject to the applicable provisions of Chapter 499, Florida Statutes, and the relevant jurisdiction of the Department.

5. Respondent neither admits nor denies the allegations in the Notice of Violation issued in case number 2022-031132, but enters into this agreement for the purpose of resolving the issues raised by the Department.

SETTLEMENT TERMS

6. Respondent affirms that it is currently in compliance with Chapter 499, Florida Statutes.

7. Respondent agrees to pay a settlement amount of six thousand dollars ($6,000.00). **Payment of the settlement amount shall be made only by corporate check, cashier's check, or money order to the Professional Regulation Trust Fund, and shall be remitted to The Florida Department of Business & Professional Regulation, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, Florida 32399-1047, Attention: Kimberley Johnson, Senior Legal Assistant**. Respondent acknowledges that payment is enclosed with this agreement. The payment and execution of this agreement by Respondent are absolute conditions precedent to the Department's execution of this agreement.

8. The acceptance of this agreement constitutes disciplinary action within the meaning of Section 499.066, Florida Statutes and Rule 61N-1.024, Florida Administrative Code.

STANDARD PROVISIONS

9. It is expressly understood that a violation of the terms of this agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary action may be taken.

10. The parties agree that this agreement will be incorporated into a final order that will be filed with the Department agency clerk and will be a public document. The final order will contain no material terms other than those in this agreement. **The final order shall operate to close case number 2022-031132. The final order shall be the final disposition in this proceeding and shall constitute final agency action with respect thereto.**

11. Respondent expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this agreement and the final order in which this agreement is incorporated, provided the final order does not conflict with this agreement.

12. Each party waives the right to seek any attorney's fees or costs from the other party in connection with this proceeding.

13. This agreement may be executed in any number of counterparts including, without limitation, telecopies and facsimile transmission copies, all of which together shall constitute a single document.

14. The parties agree that this agreement represents a fair, appropriate, and reasonable resolution to, and final disposition of, all disputes and matters made subject hereof.

15. The terms and provisions of this agreement are severable and, if any term or provision is declared or deemed void, invalid, illegal, or otherwise unenforceable, then all remaining terms and provisions shall remain in full force and effect.

16. It is expressly understood that this agreement is subject to approval of the Division of Drugs, Devices, and Cosmetics, and has no force or effect until the Division accepts this

agreement and adopts it in a final order.

17. The signatories hereto are vested with the authority to execute this agreement on behalf of their respective principals and, as duly designated representatives, to fully bind such principals.

MEDLINE INDUSTRIES, LP,

By: _____

Name: Daniel Stevens

Title: Manager Regulatory Affairs

Date: 11/18/2022

FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION DIVISION OF DRUGS, DEVICES, AND COSMETICS,

By: _____

Name: Walter Copeland

Title: Division Director

Date: 12.19.2022

Prepared by:

Anthony Coniglio
DDC Legal Chief
Division of Drugs, Devices, and Cosmetics

Attachment 1o

STATE OF OHIO
BOARD OF PHARMACY

July 19, 2023

Medline Industries, LP
c/o James Eveland
1040 Enterprise Parkway South
West Jefferson, OH 43162

Re: Settlement Agreement
License No. 01-30000190

Dear Mercy Primary Care Portage,

Enclosed you will find your Settlement Agreement with the State of Ohio Board of Pharmacy. This document is signed and effective as of July 19, 2023. If you have any questions or concerns, please do not hesitate to contact the Board of Pharmacy and ask to speak with someone in the Legal Department.

Sincerely,

Jennifer Nelson

Jennifer Nelson
Legal Administrative Assistant

Enclosure: July 19, 2023 Settlement Agreement with the State of Ohio Board of Pharmacy

CMRRR: 9414 7118 9956 2233 7395 37

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. A-2022-0307
I-2022-0168

Medline Industries, LP
c/o James Eveland
1040 Enterprise Parkway South
West Jefferson, OH 43162

License No. 01-30000190

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Medline Industries, LP, for the purpose of resolving all issues between the parties relating to the Board investigation of sales of dangerous drugs to unlicensed entities. Together, the Board and Medline Industries, LP are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Medline Industries, LP, is a licensed Distributor of Dangerous Drug, License No. 01-30000190, which lists James Eveland, as the Responsible Person.

FACTS

1. The Board initiated an investigation of Medline Industries, LP, Distributor of Dangerous Drugs License No. 01-30000190, related to Medline Industries, LP's illegal sales of dangerous drugs to an unlicensed entity.

2. On or about 11/16/2022, the Board sent a Notice of Opportunity for Hearing to Medline Industries, LP, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Medline Industries, LP neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated 11/16/2022; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Medline Industries, LP agrees to pay to the Board a monetary penalty in the amount of $875.00.00. This fine will be attached to your license record and must be paid no later than 60 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. The Board hereby imposes a written reprimand on Medline Industries, LP 's WDDD license, number 01-30000190.

5. Medline Industries, LP agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

6. Medline Industries, LP agrees to comply with all federal and state requirements related to Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Medline Industries, LP of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Medline Industries, LP by the Board and will NOT discharge Medline Industries, LP from any obligation under the terms of this Agreement.

7. Medline Industries, LP agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. Medline Industries, LP understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Medline Industries, LP will operate.

10. Medline Industries, LP waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

14. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

15. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

James Eveland, on behalf of,
Medline Industries, LP, Respondent

7-11-23
Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

Trina Buettner, RPh, President,
State of Ohio Board of Pharmacy

07.19.2023
Date of Signature

STATE OF OHIO
BOARD OF PHARMACY

July 25, 2023

Medline Industries
c/o Filomena Kropiweic
251 Hilton Dr.
Jeffersonville, IN 47130

Re: Settlement Agreement
License No. 0130000158

Dear Medline Industries,

Enclosed you will find your Settlement Agreement with the State of Ohio Board of Pharmacy. This document is signed and effective as of July 25, 2023. If you have any questions or concerns, please do not hesitate to contact the Board of Pharmacy and ask to speak with someone in the Legal Department.

Sincerely,

Jennifer Nelson

Jennifer Nelson
Legal Administrative Assistant

Enclosure: July 25, 2023 Settlement Agreement with the State of Ohio Board of Pharmacy

CMRRR: 9414 7118 9956 2027 4018 31

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE No. A-2022-0184
I-2021-1908

Medline Industries
c/o Filomena Kropiweic
251 Hilton Drive
Jeffersonville, IN 47130

License No. 01-30000158

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Medline Industries, for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of dangerous drugs to an unlicensed entity. Together, the Board and Medline Industries are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Medline Industries is a licensed Distributor of Dangerous Drug, License No. 01-30000158, which lists Filomena Kropiweic as the Responsible Person.

FACTS

1. The Board initiated an investigation of Medline Industries, Distributor of Dangerous Drugs License No. 01-30000158, related to Medline Industries' illegal sales of dangerous drugs to an unlicensed entity.

2. On or about April 25, 2023, the Board sent a Notice of Opportunity for Hearing to Medline Industries, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Medline Industries neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated April 25, 2023; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Medline Industries agrees to pay to the Board a monetary penalty in the amount of $750.00. This fine will be attached to your license record and must be paid no later than 60 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. The Board hereby imposes a written reprimand on Medline Industries' WDDD license, number 01-30000158.

5. Medline Industries agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

6. Medline Industries agrees to comply with all federal and state requirements related to Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Medline Industries of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Medline Industries by the Board and will NOT discharge Medline Industries from any obligation under the terms of this Agreement.

7. Medline Industries agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. Medline Industries understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Medline Industries will operate.

10. Medline Industries waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

14. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

15. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Filomena Kropiweic — Oct-29-2023

Filomena Kropiweic, on behalf of,
Medline Industries, Respondent

Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

07.25.2023

Trina Buettner, RPh, President,
State of Ohio Board of Pharmacy

Date of Signature

IVY Y. E. KIM 9609
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 S. Beretania Street, 9th Floor
Honolulu, Hawaii 96813
Telephone: (808) 586-2660
E-mail: ikim@dcca.hawaii.gov

Attorney for Department of Commerce
and Consumer Affairs

2023 DEC 29 P 12:37
HEARINGS OFFICE
DEPT. OF COMMERCE AND CONSUMER AFFAIRS

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Wholesale Prescription Drug Distributor License of MEDLINE INDUSTRIES, L.P., Respondent.	PHA 2023-9-L SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" – "3"

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney and Respondent MEDLINE INDUSTRIES, L.P. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was licensed as a wholesale prescription drug distributor by the Board of Pharmacy (hereinafter the "Board") under the license number PWD-193. The license was issued on or about May 16, 2022. The license will expire or forfeit on or about December 31, 2023, unless timely renewed.

2. Respondent's mailing address for purposes of this action is 2341 Lauwiliwili Street, Kapolei, Hawaii 96707.

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

3. On or about December 19, 2022, the Florida Department of Business & Professional Regulation (hereinafter "Department") issued a Final Order adopting the Settlement Agreement entered into between Respondent and the Department in Case No. 2022-031132 (hereinafter the "Florida Final Order"). The Florida Final Order was based on Respondent's alleged selling of prescription drugs to an unauthorized recipient, failure to maintain records, and failure to provide required documentation to customers. The Florida Final Order is attached hereto as Exhibit "1".

4. On or about July 19, 2023, Respondent and State of Ohio Board of Pharmacy entered into a Settlement Agreement in Case No. A-2022-0307, I-2022-0168, related to Respondent's illegal sales of dangerous drugs to an unlicensed entity. The Settlement Agreement is attached hereto as Exhibit "2".

5. On or about July 25, 2023, Respondent and State of Ohio Board of Pharmacy entered into a Settlement Agreement in Case No. A-2022-0184, I-2021-1908, related to Respondent's illegal sales of dangerous drugs to an unlicensed entity. The Settlement Agreement is attached hereto as Exhibit "3".

6. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes (hereinafter "HRS") § 436B-19(13) (disciplinary action by another state or federal agency).

7. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing, and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent, being at all times relevant herein licensed as a wholesale prescription drug distributor by the Board, acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the license and administrative fines, if the foregoing allegations are proven at hearing. Respondent further understands that RICO enters into this Settlement Agreement and agrees to the specific terms contained in this Settlement Agreement, based upon Respondent's representations made herein.

5. Respondent represents that Exhibits "1" – "3" are true and correct copies of the purported Florida Final Order and Settlement Agreements with the Ohio Board of Pharmacy.

6. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this Settlement Agreement may be grounds for further disciplinary action under HRS Chapters 436B and 461.

7. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's license.

8. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

9. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2023-9-L.

10. Respondent understands that this Settlement Agreement may be subject to reporting requirements.

11. Respondent understands this Settlement Agreement is public record pursuant to HRS Chapter 92F.

12. Respondent acknowledges that upon tis approval, this Settlement Agreement constitutes disciplinary action.

C. TERMS OF SETTLEMENT:

1. Administrative Fine. Respondent agrees to pay an administrative fine in the amount of TWO THOUSAND TWO HUNDRED FIFTY AND NO/100 DOLLARS ($2,250.00). Payment shall be made by **cashier's check or money order made payable to "DCCA – Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn.: Ivy Y. E. Kim, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph C.1. above, Respondent's license shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of licensure to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new license until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become licensed again, Respondent must apply to the Board for a new license pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible Further Sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board

may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of pharmacies in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5., C.6., and C.7. below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent, nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion, or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion, or promise made by RICO or any of its agents, employees, representatives, or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

[Remainder of this page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below. Each signatory to this Settlement Agreement hereby represents and warrants that he/she is authorized to execute and deliver this Settlement Agreement in the capacity shown below.

DATED: Northfield (City), IL (State), 09/07/2023 (Date).

MEDLINE INDUSTRIES, L.P.
Respondent

By: _____ (Signature)

Daniel Stevens (Print Name)

Its Manager Regulatory Affairs (Print Title)

DATED: Honolulu, Hawaii, 10/11/2023.

IVY Y. E. KIM
Attorney for Department of Commerce
and Consumer Affairs

IN THE MATTER OF THE WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR LICENSE OF MEDLINE INDUSTRIES, L.P.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" – "3"; RICO CASE NO. PHA 2023-9-L.

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

ALANNA ISOBE Chair	December 21, 2023 **DATE**
PATRICK ADAMS Vice Chair	**MARK BROWN**
CATALINA CROSS	Kent Kikuchi **KENT KIKUCHI**
BRANDON RABANG	**SHERI TOKUMARU**

PVL 11/09/22

POWER OF ATTORNEY

MEDLINE INDUSTRIES, LP, an Illinois limited partnership, having a principal place of business at 3 Lakes Drive, Northfield, Illinois, 60093 (the "Company"), herewith authorize and entrust a Power of Attorney to DANIEL A. STEVENS, United States citizen, Manager Regulatory Affairs, with permanent residence at 4217 Arlington Avenue, Sacramento, CA 95820 with full signatory rights on behalf of the Company as follows:

To be our true and lawful Agent with as full as legally necessary powers to submit, execute and prosecute applications in the name of the Company, for permits, registrations and other governmental authorizations, relating in any way to the quality assurance, quality control, regulatory, warehousing and sterilizing functions of the Company, and to represent the Company and take all necessary actions in legal matters and all other matters towards all third parties and all public authorities, federal, state or municipal, and towards all other divisions, subdivisions, departments, units or all secretariats of the above, relating in any way to the quality assurance, quality control, regulatory, warehousing and sterilizing functions of the Company.

This power of Attorney is valid until revoked in writing by the Company.

Dated: October 11, 2022

Medline Industries, LP

By: Mozart GP, LLC
Its: General Partner

By: _____
Name: Alexander M. Liberman
Title: Assistant Secretary

ACKNOWLEDGEMENT

STATE OF ILLINOIS
COUNTY OF COOK

This instrument was acknowledged before me on October 11, 2022 by Alexander M. Liberman, as Assistant Secretary of Mozart GP, LLC, as General Partner of Medline Industries, LP.

Barbara Bychowski
(Signature of Notary Public)

(Seal)

"OFFICIAL SEAL"
BARBARA BYCHOWSKI
NOTARY PUBLIC, STATE OF ILLINOIS
MY COMMISSION EXPIRES 8/29/2025

4H

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10)

Section 1: General Information

Facility Name: Medline Industries, LP

Physical Address: 9375 W Sugar Road

City: Tracy State: CA Zip: 95304

Mailing Address (if different from physical address): Three Lakes Drive- Attn Licensing 3D

City: Northfield State: IL Zip: 60093

Telephone: (916) 292-0005 Website: www.medline.com

Name of Designated Representative (DR): Johnny Glover

Licensing Company Email: ralicensing@medline.com DR Email: jrglover@medline.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies ■ Practitioners ■ Hospitals ■ Wholesalers ■ Veterinarians ■ Others: Post Acute	■ Dangerous Drugs ☐ Controlled Substances ■ [a]Medical Products (medical devices, equipment, supplies, gases) ☐ Others:	☐ Manufacturer ☐ Repacker ☐ Reverse Distributor ■ Warehouse ☐ Retail pharmacy wholesale distributor ☐ Others:

Section 2: ONLY COMPLETE THIS SECTION IF THE COMPANY IS WHOLESALING ª Medical Products (medical devices, equipment, supplies and gases). Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 3 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

See attached

Original Signature (electronic, copies or stamps not accepted)

09/02/2026

Date

Section 4: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Pfizer, Inc.
Address: 66 Hudson Blvd E City: New York State: NY Zip: 10001

Name: ICU Medical Inc.
Address: 951 Calle Amanecer City: San Clemente State: CA Zip: 92673

Name: Baxter Healthcare Inc.
Address: One Baxter Parkway City: Deerfield State: IL Zip: 60015

Name: B Braun Medical Inc.
Address: 824 12th Avenue City: Bethlehem State: PA Zip: 18018

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any):
Corporation Name: Medline Inc.
Mailing Address: 3 Lakes Drive
City: Northfield State: IL Zip: 60093
Telephone: (847) 949-5500 Email: ralicensing@medline.com
Contact Person Name: Daniel Stevens

Date of SEC Registration: 12/17/2025 | SEC Registration Number: 0002046386 | Stock Exchange Symbol: MDLN

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 8: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 9: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 10: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale [a]Medical Products (medical devices, equipment, supplies, gases). (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Products (medical devices, equipment, supplies, gases), supply a copy of proof of insurance (NAC 639.6957).** The Medical Products wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 9)				
• **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20NRS%20639.500%20-%20Effective%2001.07.2026%20-%20Wholesaler%20-%20Post%20on%201.26.26.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Medline Industries, LP

Facility Name

Daniel Stevens

Print Name of Authorized Person Submitting Application

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

09/02/2026

Date

Board Use Only	Date Received: 9/4/26	Amount: $1000 cc

POWER OF ATTORNEY

MEDLINE INDUSTRIES, LP, an Illinois limited partnership, having a principal place of business at 3 Lakes Dr, Northfield, Illinois, 60093 (the "Company"), herewith authorizes and entrusts a Power of Attorney to DANIEL A. STEVENS, United States citizen, Manager, Regulatory Affairs, with permanent residence at 4369 Vulcan Drive, Sacramento, California 95864 with full signatory rights on behalf of the Company as follows:

To be our true and lawful Agent with as full as legally necessary powers to submit, execute and prosecute applications in the name of the Company, for permits, registrations and other governmental authorizations, relating in any way to the quality assurance, quality control, regulatory, warehousing, distribution, licensing, and sterilizing functions of the Company, and to represent the Company and take all necessary actions in legal matters and all other matters towards all third parties and all public authorities, federal, state or municipal, and towards all other divisions, subdivisions, departments, units or all secretariats of the above, relating in any way to the quality assurance, quality control, regulatory, warehousing, distribution, licensing, and sterilizing functions of the Company.

This Power of Attorney is valid until revoked in writing by the Company.

Dated: January 21, 2026

Medline Industries, LP
By: Mozart GP, LLC
Its: General Partner

By: ML
Name: Alexander M. Liberman
Title: Chief Legal Officer and Secretary

ACKNOWLEDGEMENT

STATE OF ILLINOIS
COUNTY OF COOK

This instrument was acknowledged before me on January 21, 2026 by Alexander M. Liberman, as Chief Legal Officer and Secretary of Mozart GP, LLC, as General Partner of Medline Industries, LP.

Barbara Theresa Bychowski
(Signature of Notary Public)

(Seal)

OFFICIAL SEAL
Barbara Theresa Bychowski
NOTARY PUBLIC, STATE OF ILLINOIS
Commission No. 1018211
My Commission Expires August 28 2029

Medline Inc.

FEIN: IL 33-185288

Contact Information:
3 Lakes Drive
Attn: RA Licensing – 3D
Northfield, IL 60093
Ralicensing@medline.com
847-949-5500

Officers and Directors:
Information as of 09/01/2026

Officers

Name	Title
James M. Boyle	Chief Executive Officer
Michael B. Drazin	Chief Financial Officer
Stephen L. Miller*	Chief Operating Officer
Alexander M. Liberman	Chief Legal Officer
Douglas P. Golwas	Chief Commercial Officer
Christopher P. Shryock	Chief Human Resources Officer
Amanda Hutton Laabs	Chief Product Officer
Jessi Corcoran	Chief Accounting Officer
William J. Abrams	Executive Vice President, Supply Chain Solutions

*On July 7, 2026, Stephen L. Miller, Chief Operating Officer of Medline Inc. (the "Company"), notified the Company that he would retire from his role, effective August 30, 2026. A search is ongoing for his successor.

Directors

Name	Title
Charles N. Mills	Non-Executive Chair of the Board
Andrew J. Mills	Director
Anushka M. Sunder	Director
Jacob D. Best	Director
James M. Boyle	Director
Joseph P. Baratta	Director
Patrick J. Healy	Director
Richard A. Galanti	Director
Robert R. Schmidt	Director
Stephen H. Wise	Director
Thomas W. Sweet	Director
Todd N. Bluedorn	Director

Medline Inc.
Top Four Shareholders

Medline Inc.
Medline Inc. is a U.S. publicly traded company trading under the ticker symbol MDLN on Nasdaq. Medline Inc. publicly reports beneficial holders of 5% or more of its outstanding securities ("significant stockholders") in its filings with the U.S. Securities and Exchange Commission ("SEC"), which are available at www.sec.gov/edgar/browse/?CIK=2046386. Medline Inc. reports this information in accordance with SEC rules, including in reliance on public reporting of ownership by its significant stockholders.

Top Four Shareholders of Medline Inc. as of May 4, 2026

Name of Beneficial Owner	Combined Voting Power
Mozart HoldCo, Inc.[1]	17.8%
Blackstone[2]	14.2%
Carlyle[3]	14.2%
H&F[4]	14.2%

[1] Mozart HoldCo, Inc. is an entity that is owned directly and/or indirectly by members of the Mills Family and trusts for their benefit.
[2] "Blackstone" refers to certain entities and/or funds associated with Blackstone Inc.
[3] "Carlyle" refers to certain entities and/or funds associated with The Carlyle Group Inc.
[4] "H&F" refers to certain entities and/or funds associated with Hellman & Friedman LLC

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "MEDLINE INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRD DAY OF APRIL, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "MEDLINE INC." WAS INCORPORATED ON THE SIXTH DAY OF NOVEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5143163 8300

SR# 20261572157

Authentication: 203550646

Date: 04-03-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

File Number S030704

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, Alexi Giannoulias, *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

MEDLINE INDUSTRIES, LP, HAVING REGISTERED IN THE STATE OF ILLINOIS ON SEPTEMBER 07, 2021, APPEARS TO HAVE COMPLIED WITH ALL PROVISIONS OF THE UNIFORM LIMITED PARTNERSHIP ACT (2001) OF THIS STATE, AND AS OF THIS DATE IS IN GOOD STANDING AS A DOMESTIC LP/LLLP IN THE STATE OF ILLINOIS, HAVING FULFILLED ALL REQUIREMENTS OF SAID ACT WITH REGARD TO PAYMENT OF FEES, THE FILING OF ANNUAL REPORTS (IF APPLICABLE) AND NEITHER HAVING BEEN ADMINISTRATIVELY DISSOLVED BY THE SECRETARY OF STATE NOR HAVING VOLUNTARILY FILED A STATEMENT OF TERMINATION.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 15TH *day of* APRIL *A.D.* 2026 .

SEAL OF THE STATE OF ILLINOIS — AUG. 26TH 1818

Authentication #: 2610502528 verifiable until 04/15/2027
Authenticate at: https://www.ilsos.gov

Alexi Giannoulias
SECRETARY OF STATE

BOARD OF PHARMACY

LICENSING DETAILS FOR: WLS 8959

NAME: MEDLINE INDUSTRIES LP

LICENSE TYPE: WHOLESALER

LICENSE STATUS: CLEAR

ADDRESS

9375 W SUGAR RD
TRACY CA 95304
SAN JOAQUIN COUNTY

ISSUANCE DATE

SEPTEMBER 14, 2026

EXPIRATION DATE

DECEMBER 15, 2026

CURRENT DATE / TIME

SEPTEMBER 15, 2026
5:20:22 AM

LICENSE RELATIONSHIPS

NAME: GLOVER II, JOHNNY RAY

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: DESIGNATED REPRESENTATIVE (WHOLESALER)

LICENSE NUMBER: 27670 **PRIMARY STATUS:** CLEAR

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 09/21/2026

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

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

PRODUCER MARSH USA LLC 155 N. WACKER, SUITE 1200 CHICAGO, IL 60661 CN101705524-Strid-GAWUP-26-27 USA	**CONTACT NAME:** Medline Industries, LP **PHONE (A/C, No, Ext):** **FAX (A/C, No):** **E-MAIL ADDRESS:** riskmanagement@medline.com
INSURED Medline Industries, LP 3 Lakes Dr Northfield, IL 60093	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** Safety National Casualty Corporation — 15105 **INSURER B :** Endurance Assurance Corporation — 11551 **INSURER C :** Life Science Risk — 23582 **INSURER D :** **INSURER E :** **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** CHI-008956355-50 **REVISION NUMBER:** 86

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			GL 4065036	07/01/2026	07/01/2027	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ $ $ $ $ $	2,000,000 2,000,000 10,000 2,000,000 4,000,000 SEE BELOW
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			CA 6675933	07/01/2026	07/01/2027	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $	2,000,000
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $ 10,000			ELD10004065213	07/01/2026	07/01/2027	EACH OCCURRENCE AGGREGATE	$ $	10,000,000 10,000,000
A A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y / N: Y If yes, describe under DESCRIPTION OF OPERATIONS below	N / A		LDS 4065032 (AOS) PS 4065034 (WI)	07/01/2026 07/01/2026	07/01/2027 07/01/2027	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $	1,000,000 1,000,000 1,000,000
C	Products/Completed Operations Liability			LSR-PCO-00678-26	07/01/2026	07/01/2027	Limit		2,000,000

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

Re: C42 - 3446 Highway 51 N Southaven, MS 38672. C40- 81 Campanelli Dr, Uxbridge, MA 01569, A29 – 10585 County Road 101, Corcoran, MN 55314, C77 – 9375 W. Sugar Rd., Tracy, CA 95304.
SIR applies per policy terms & conditions. The products/completed operations policy evidenced above is subject to self-insured retentions for various perils covered.
Evidence of Insurance.

CERTIFICATE HOLDER

Medline Industries, LP
3 Lakes Dr.
Northfield, IL 60093

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

© 1988-2016 ACORD CORPORATION. All rights reserved.

AGENCY CUSTOMER ID: CN101705524
LOC #: Chicago

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC.	Medline Industries, LP 3 Lakes Dr Northfield, IL 60093
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

LOCATION ADDRESS CITY STATE ZIP CODE
B01 1 Medline Pl. Mundelein Illinois 60060
B04 1160 S Northpoint Blvd S . Waukegan Illinois 60085
B04 1710 S Lakeside Dr. Waukegan Illinois 60085
B04 1170 S Northpoint Blvd S. Waukegan Illinois 60085
B06 1 Medline Dr. Wilmer Texas 75172
B11 21111 E 36th Dr. Aurora Colorado 80011
B18 1062 Fasken Blvd. Laredo Texas 78045
B22 9670 NW 112 Ave. Medley Florida 33178
B24 8001 SW 47th St. Oklahoma City Oklahoma 73179
B25 1401 N Universal Ave. Kansas City Missouri 64120
B27 92 SE 223rd Ave. Gresham Oregon 97030
B28 735 County Rd 4 E. Prattville Alabama 36067
B29 13115 Brockton Lane N. Rogers Minnesota 55374
B30 1900 Meadowville Technology Parkway. Chester Virginia 23836
B31 500 Sharkey Dr. Maumelle Arkansas 72113
B34 9051 King St. Anchorage Alaska 99518
B36 1989 Transit Way. Brockport New York 14420
B44 2325 W Louise Ave. Manteca California 95337
B45 1119 W Middlesex Ave Bldg 4. Port Reading New Jersey 07064
B48 36445 Van Born Road. Suite 200 Romulus Michigan 48174
B49 42500 Winchester Rd. Temecula California 92590
B56 190 Medline Drive, Suite 200. Richmond Hill Georgia 31324
B66 2700 E. Imperial Highway Lynwood California 90262
B80 2341 Lauwiliwili St, Suite 107 Kapolei Hawaii 96707
B82 9103 Riverside Parkway Lithia Springs Georgia 30122
C02 2200 Cornerstone Parkway. Grayslake Illinois 60030
C03 1500 Medline Pl. McDonough Georgia 30253
C05 1062 Old Dixie Highway. Auburndale Florida 33823
C09 1960 W Miro Way. Rialto California 92376
C32 29895 US Hwy 90 Bus. Katy Texas 77494
C37 5000 Premier Parkway. St. Peters Missouri 63376
C40 81 Campanelli Dr. Uxbridge Massachusetts 01569
C41 1040 Enterprise Parkway South. West Jefferson Ohio 43162
C42 3446 Highway 51 N. Southaven Mississippi 38672
C46 5701 Promontory Parkway. Suite 100 Tracy California 95377
C47 239 Belvidere Rd. Perryville Maryland 21903
C50 8787 W Buckeye Ave. Tolleson Arizona 85353
C54 494 State Route 416. Montgomery New York 12549
C57 5511 W Ten Rd. Mebane North Carolina 27302
C59 2100 Industrial Park Road Hammond Louisiana 70401
C71 264 S 5750 W. Salt Lake City Utah 84104
C75 3770 Hogum Bay Rd NE. Lacey Washington 98516
C89 251 Hilton Dr. Jeffersonville Indiana 47130
RCH - Hartland, WI 700 W North Shore Dr. Hartland Wisconsin 53029
D46 - Lathrop, CA 18601 Christopher Way Ste 100. Lathrop California 95330
MXC - SPT 16415 Cosmos St. Moreno Valley California 92551
ANGIO 10 Glen Falls Technical Park. Glen Falls New York 12801
E22 600 Derby Ave West Haven Connecticut 06516
E23 3835 John Wall Dr Madison Wisconsin 53704

© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: CN101705524
LOC #: Chicago

ACORD®

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC.	Medline Industries, LP 3 Lakes Dr Northfield, IL 60093
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

E26 1390 Sparrows Point Blvd Ste700 Edgemere Maryland 21219
LRD 12001 General Milton Dr. Laredo Texas 78045
A29 - 10585 County Road 101, Corcoran, MN 55314
C77 – 9375 W Sugar Road, Tracy, CA 95304

© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

GENERAL SURETY RIDER

To be attached and form a part of

Type of Bond: License & Permit

Bond No. : 105625536

Dated effective: 7/20/2015
(MONTH, DAY, YEAR)

executed by: Medline Industries, LP, as Principal,
(PRINCIPAL)

and by: Travelers Casualty and Surety Company of America, as Surety,
(SURETY)

and in favor of : Nevada State Board of Pharmacy .
(OBLIGEE)

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

Add Location: Medline Industries, LP, (C77) - 9375 W. Sugar Road, Tracy, CA 95304

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective 9/2/2026
(MONTH, DAY, YEAR)

Signed and Sealed 9/2/2026
(MONTH, DAY, YEAR)

Travelers Casualty and Surety Company of America
SURETY

BY: Oscar F. Rincon
Oscar F. Rincon, ATTORNEY-IN-FACT

TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA ★ SEAL

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company

POWER OF ATTORNEY

Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, and St. Paul Fire and Marine Insurance Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and the Companies do hereby make, constitute and appoint **Oscar F. Rincon** of **ROLLING MEADOWS**, **Illinois**, their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **13th** day of **May**, **2026**.

SEAL SEAL SEAL

State of Connecticut

By: _____
Bryce Grissom, Senior Vice President

City of Hartford ss.

On this the **13th** day of **May**, **2026**, before me personally appeared **Bryce Grissom**, who acknowledged himself to be the Senior Vice President, Surety, Bond & Specialty Insurance, of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **31st** day of **March**, **2031**

NOTARY PUBLIC

_____
Marie E. Sorensen, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 2nd day of September, 2026

SEAL SEAL SEAL SEAL

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

ACKNOWLEDGMENT BY SURETY

STATE OF Illinois }
County of Kendall } ss.

On this 2nd day of September, 2026, before me personally appeared Oscar F. Rincon, known to, me to be the Attorney-in-Fact of Travelers Casualty and Surety Company of America, the corporation that executed the within instrument, and acknowledged to me that such corporation executed the same.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal, at my office in the aforesaid County, the day and year in this certificate first above written.

Gina Marie Damato
Notary Public in the State of Illinois
County of Kendall

OFFICIAL SEAL
GINA MARIE DAMATO
Notary Public, State of Illinois
Commission No. 990704
My Commission Expires
May 13, 2028

S-0230/GE 10/99

TRAVELERS

VERIFICATION CERTIFICATE

License No. _____

Bond No.: **105625536**

Current Billing Term From **July 20, 2026** to **July 20, 2027**

THIS IS TO CERTIFY that the above referenced Bond,

issued by **Travelers Casualty and Surety Company of America**,

dated **July 20, 2011**, in the amount of **One Hundred Thousand ($100,000.00)** on behalf of

MEDLINE INDUSTRIES, LP (as Principal),

and in favor of **Nevada State Board of Pharmacy** (as Obligee),
remains in effect, subject to all agreements, conditions and limitations.

Signed, sealed and dated **April 11, 2026**

Travelers Casualty and Surety Company of America

By: _____
Peter S Forker Attorney-in-Fact

TRAVELERS CASUALTY AND SURETY COMPANY OF AMERICA
HARTFORD, CONN.

F-307-J (10/68)
(Rev. 05/16)

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company
Farmington Casualty Company

POWER OF ATTORNEY

Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, St. Paul Fire and Marine Insurance Company, and Farmington Casualty Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and the Companies do hereby make, constitute and appoint **Peter S Forker** of **ROLLING MEADOWS, IL** their true and lawful Attorney(s)-in-Fact to sign, execute, seal and acknowledge the following bond or undertaking, and any riders thereto:

Surety Bond No.: 105625536 **Principal: MEDLINE INDUSTRIES, LP**

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **13th** day of **May, 2026.**

State of Connecticut

City of Hartford ss.

By: _____
Bryce Grissom, Senior Vice President

On this the **13th** day of **May, 2026**, before me personally appeared **Bryce Grissom**, who acknowledged himself to be the Senior Vice President, Surety, Bond & Specialty Insurance, of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **31st** day of **March, 2031**

_____
Marie E. Sorensen, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 11 day of April, 2026.

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney(s)-in-Fact and the details of the bond to which this Power of Attorney is attached.

ACKNOWLEDGMENT BY SURETY

STATE OF Illinois }
County of Cook } ss.

On this 11th day of April, 2026, before me personally appeared Peter S. Forker, known to, me to be the Attorney-in-Fact of Travelers Casualty and Surety Company of America, the corporation that executed the within instrument, and acknowledged to me that such corporation executed the same.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal, at my office in the aforesaid County, the day and year in this certificate first above written.

OFFICIAL SEAL
OSCAR F RINCON
NOTARY PUBLIC, STATE OF ILLINOIS
COMMISSION NO. 513016
MY COMMISSION EXPIRES FEBRUARY 20, 2029

Oscar F. Rincon

Notary Public in the State of Illinois
County of Cook

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Medline Industries, LP — MDEG License # (if applicable): _____

Physical Address: 9375 W Sugar Road

City: Tracy — State: CA — Zip: 95304

Mailing Address (if different from physical address): Three Lakes Drive- Licensing 3D

City: Northfield — State: IL — Zip: 60093

Telephone: (916) 292-0005 — Website: www.medline.com

Licensing Company Email: ralicensing@medline.com

Section 2: Personal Information

First: Johnny — Middle: Ray — Last: Glover II

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

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

Mailing Addre[redacted]

City: Manteca — State: CA — Zip: [redacted]

Telephon[redacted] — Email: JRGlover@medline.com

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

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

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

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

School Name			From - To (MM/YY – MM/YY)
Eastern New Mexico University			01/04 - 12/05
Address	**City**	**State**	**Zip**
1500 S Ave K	Portales	NM	88130
Diploma/Degree obtained, if any			
Bachelors			

School Name			From - To (MM/YY – MM/YY)
University of New Mexico			08/03 - 12/03
Address	**City**	**State**	**Zip**
1 University of New Mexico	Albuquerque	NM	87131
Diploma/Degree obtained, if any			
N/A			

School Name			From - To (MM/YY – MM/YY)
New Mexico Military Institute			08/01 - 05/03
Address	**City**	**State**	**Zip**
101 W. College Blvd	Roswell	NM	88201
Diploma/Degree obtained, if any			
Bachelors			

School Name			From - To (MM/YY – MM/YY)
Lovington High School			08/97- 05/01
Address	**City**	**State**	**Zip**
7041 W. Ave K	Lovington	NM	88260
Diploma/Degree obtained, if any			
HS Diploma			

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/23 - present	[redacted]	Manteca	CA	[redacted]
10/22 - 05/23		Tracy	CA	
08/17 - 10/22		Moreno Valley	CA	
08/16 - 08/17		Olathe	KS	
12/13- 08/16		Victorville	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Medline Industries, LP			08/22- Present	
Business Address		**City**	**State**	**Zip**
5701 Promontory Parkway,Ste#100		Tracy	CA	95377
Phone	**Title**		**Number of Employed Hours**	
(800) 633-5463	Senior Director Operations		8,320	
Description of Duties				
Oversee warehouse operations (receiving, storage, shipping, etc.) for drug and medical device distribution.				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

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

I, Johnny Glover, **certify that as the MDEG Administrator for**

Medline Industries, LP,

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

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

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

Johnny Glover
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/2/2026
Date

Board Use Only	Date Received: 9/9/26

List of Employees
Medline Industries, LP
C77 - Tracy, CA (tenative list)

Worker	Business Title	Worker	Business Title
Aaron Anacleto	Warehouse Operator Operations	Angel Valora [C]	Warehouse Operator
Aaron Carranza	Warehouse Ld Operations	Angelo Arenas	Warehouse Operator Operations
Aaron Gipson	Warehouse Operator Operations	Angie Harriman	Warehouse Operator Operations
Abigail Ibarra	Delivery Driver	Aniyah Wilson	Warehouse Operator Operations
Abraham Hernandez	Warehouse Operator Operations	Anthony Aiello	Warehouse Operator Operations
Adam Mcclanahan	Warehouse Operator Operations	Anthony Demag	Driver II
Adrian Garza	Warehouse Operator Operations	Anthony Jimenez	Warehouse Operator Operations
Adrian Soto Sarabia	Warehouse Operator Operations	Anthony Sobarzo	Warehouse Operator Operations
Adrian Vega Ramirez	Warehouse Operator Operations	Anthony Zaldivar	Supv Warehouse
Adriana Medina	Warehouse Operator Operations	Antonio Barraza	Warehouse Operator Operations
Ahmed Hussain	Delivery Driver	Antonio Catolos	Warehouse Operator Operations
Aj Atkinson	Warehouse Operator Operations	Antonio Garcia	Warehouse Operator Operations
Al Alonzo	Warehouse Operator Operations	Antonio Tapia	Warehouse Operator Operations
Alan Flanagan	Supv Warehouse	Anuradha Chaganti	Sr Analyst Financial
Alan King	Warehouse Operator Operations	April Pruitt	Warehouse Operator Operations
Alana De Leon	Inventory Coord Sr	Araceli Solis	Warehouse Operator Operations
Alana Salas	Warehouse Operator Operations	Armando Anguiano	Supv Warehouse
Alejandro Nolazco	Warehouse Operator Operations	Armando Garcia	Warehouse Operator Operations
Alejo Gonzales	Trainer Branch	Arsenio Amigable	Warehouse Operator Operations
Alenia Adams	Warehouse Operator Operations	Arthur Hawkins	Trainer Branch
Alessandro Mcintyre	Delivery Driver	Arturo Castro	Driver Ld
Alex Carrillo	Shuttle Driver	arturo Ramirez	Warehouse Operator Operations
Alex Davis	Warehouse Operator Operations	Aryan Ryan	Warehouse Ld Operations
Alex Nunez Jr.	Warehouse Operator Operations	Arzely Caulawon	Inventory Coord Operations
ALEXA TORRES	Warehouse Operator Operations	Arzenith Macadildig	Warehouse Operator Operations
Alexander Francis	Warehouse Operator Operations	Ashanti Hall	Supv QC
Alexander Ramirez chavez	Driver II	Ashley Lopez	Supv Warehouse
Alexis Brown	Warehouse Operator Operations	Audiel Munoz Quiroz	Supv Inventory Control
Alfonso Perez	Janitor Operations	Aura Rebollar	Warehouse Operator Operations
Alfredo Fonseca [C]	Warehouse Operator	Axl Dombrain	Warehouse Operator Operations
ALFREDO RODRIGUEZ	Warehouse Operator Operations	AZELIA MCKENZIE (On Leave)	Warehouse Operator Operations
Allyza Manzano	Warehouse Operator Operations	B clark	Warehouse Operator Operations
Alma Maciel Gutierrez	Warehouse Operator Operations	Balbir Kaur	Warehouse Operator Operations
Alyssa Massa	Warehouse Operator Operations	Baljinder Kaur	Warehouse Operator Operations
Alyssa Rubio	Warehouse Operator Operations	Baltazar Galvan	Driver I
Amandeep Kaur	Warehouse Operator Operations	Barbara Gonzalez	Warehouse Operator Operations
Amit Nath	Warehouse Operator Operations	Beaney Cervantes	Warehouse Operator Operations
Ana Hernandez	Warehouse Operator Operations	Beatriz Acevedo Tafolla	Warehouse Operator Operations
ANA SICAIROS	Warehouse Operator Operations	Belinda James	Warehouse Operator Operations
Anastacia Rose	Warehouse Operator Operations	Belinda Tanique Cruz	Inventory Coord Operations
Andre Augustin	Warehouse Operator Operations	Benjamin Magana	Driver II
Andre Martinez	Warehouse Operator Operations	Benjie Maningding	Warehouse Operator Operations
Andre Taylor	Maintenance Ld	Bennie Jucutan	Warehouse Operator Operations
Andrea Jill Flauta	Warehouse Operator Operations	Bernardo Villapudua (On Leave)	Warehouse Operator Operations
Andrea Lopez	Warehouse Operator Operations	Betsy Rodriguez	Warehouse Operator Operations
Andrew Deocampo	Warehouse Operator Operations	Bhella Jones	Warehouse Operator Operations
Anel Reyes Jaimes	Warehouse Operator Operations	Bianca Moreno	Warehouse Operator Operations
Angel Jesuitas	Mgr Warehouse	Blanca Arellano	Warehouse Operator Operations
Angel Silva-Maciel	Warehouse Operator Operations	Bobbi-Jo Mattson	Warehouse Operator Operations

BORY Al	Warehouse Operator Operations
Brandon Crabb	Janitor Operations
Brandon Flores	Warehouse Operator Operations
Brenda Olimpia Garcia De Soto	Janitor Operations
Brian Manzer	Mgr Maintenance
Brian Torres	Warehouse Operator Operations
Buree Nhoung	Warehouse Operator Operations
Cameron Degrafenread	Warehouse Operator Operations
Carlos Sanchez santamaria	Warehouse Operator Operations
Carlos Villa	Warehouse Operator Operations
Carven Evans	Driver II
Casey Envia	Warehouse Operator Operations
Cassandra Falepouono	Warehouse Operator Operations
Cassaundra Clark	Warehouse Operator Operations
Cat Cardoza	Warehouse Operator Operations
Catalina Bocanegra	Warehouse Operator Operations
Cerena Carrisosa	Supv Warehouse
Cerina Vilayphone	Warehouse Operator Operations
Cesar Aguayo	Driver Ld
Cesar Alvarez	Warehouse Operator Operations
Cesar Maciel	Driver II
Cesar Valencia Barragan	Warehouse Operator Operations
Cha Vang	Delivery Driver
Chad Mcdonald	Warehouse Operator Operations
Chandler Goodrich	Warehouse Ld Operations
Chania Morris	Warehouse Operator Operations
Charity Fulgueras	Inventory Coord Sr
Charles Loudermilk	Warehouse Operator Operations
Charles Morris	Warehouse Operator Operations
Charles Morris	Maintenance Ld
Charles Reed	Driver II
Charles Stover	Warehouse Operator Operations
Cheryl Sweezer	Warehouse Operator Operations
Chia Vang	Warehouse Operator Operations
Chris Harrison	Warehouse Operator Operations
Chris Sanchez	Driver II
Chris Sansom	Maintenance Tech I
Christian Gutierrez	Warehouse Operator Operations
Christian Losoya	Supv MedTrans
Christina Maldonado	Warehouse Operator Operations
Christine King-Sablan	Warehouse Operator Operations
Christopher Baker	Driver II
Christopher Brocco [C]	Driver II
Christopher Brown	Warehouse Operator Operations
Christopher Graham	Warehouse Operator Operations
Christopher Sanchez	Driver II
Cierria Garrison (On Leave)	Warehouse Operator Operations
Citlali Zavala	Warehouse Operator Operations
Clifton Holliday	Janitor Operations
Cody Harris	Driver II
Colt Gonzales	Inventory Coord Operations
Cristhian Valenzuela	Warehouse Operator Operations
Cristian Guillen	Warehouse Operator Operations
Cristina Barber	Warehouse Operator Operations
Cristofer Gamez	Warehouse Operator Operations
Cristopher Garcia Terrones	Warehouse Ld Operations
Crystal De Los Reyes	Sr Spec EH&S
Crystal Pimentel (On Leave)	Warehouse Operator Operations
CURTIS ANDERSON	Warehouse Operator Operations
Cynthia Mcdonald	Warehouse Operator Operations
D.D. Duenas	Warehouse Operator Operations
Daiquan Howard	Warehouse Operator Operations
Daisy Zaragoza	Inventory Coord Operations
Dakota Hotel-Garcia	Quality Control Inspector II
Damare Lawson	Warehouse Operator Operations
Damarea Gaines	Warehouse Operator Operations
Damaris Sevilla (On Leave)	Warehouse Operator Operations
Damariz Alvarez	Supv Warehouse
Damien Skaggs	Warehouse Operator Operations
Damoria Adams	Warehouse Operator Operations
Dan Phimmasone	Janitor Operations
Danaejah Banks	Warehouse Operator Operations
Dani Vera Bustamante	Warehouse Clerk Operations
Daniel Anastacio Garcia	Warehouse Operator Operations
Daniel Garcia	Warehouse Operator Operations
Daniel Manzo	Warehouse Operator Operations
Daniel Mendez	Warehouse Operator Operations
Daniel Ramirez	Driver II
Daniel Rodriguez	Driver I
Daniel Zacarias	Warehouse Operator Operations
Daniella Walker	Warehouse Operator Operations
Daniyal Ali	Warehouse Operator Operations
Danny Diaz	Warehouse Operator Operations
Danny Lo	Inventory Coord Sr
Danny Santiago	Supv Warehouse
Darryl Womack	Warehouse Operator Operations
Darwin Baquero	Driver II
Davian Montgomery (On Leave)	Warehouse Operator Operations
David Bautista	Warehouse Operator Operations
David Bellamy	Warehouse Operator Operations
David Brionez	Warehouse Operator Operations
David Dumanon	Warehouse Operator Operations
DAVID FULLER	Warehouse Operator Operations
David Martinez	Warehouse Operator Operations
David Martinez	Warehouse Operator Operations
David Mayfield	Driver Ld
David Nwaonumah	Warehouse Operator Operations
David Pena	Driver II
David Smith	Janitor Operations
Davith Moeun	Warehouse Operator Operations
Dawnfrances Reyes	Warehouse Operator Operations
De'Onicio Wilson	Warehouse Operator Operations
Deamian Collins	Warehouse Operator Operations
Dee Bey	Mgr Warehouse
Deion Nicolas	Warehouse Ld Operations
Deja Mayfield	Supv Warehouse
Delia Medina (On Leave)	Warehouse Operator Operations
Delores Hedgemon	Warehouse Operator Operations

Demi Saenz	Supv Warehouse	Enrique Perez	Warehouse Operator Operations
Denise Montinola	Warehouse Operator Operations	Eric Barojas Contreras	Warehouse Operator Operations
Derrick Martin	Warehouse Operator Operations	Eric McRae	Sr Supv Warehouse
Desiree Lopez	Supv Warehouse	Eric Nava	Warehouse Operator Operations
Dessy Alvizo	Warehouse Operator Operations	Eric Olvera Carmona	Warehouse Operator Operations
Destiny Duran	Warehouse Operator Operations	Erick Tafolla Aguilar	Warehouse Operator Operations
Devon Sam	Warehouse Operator Operations	Erik Becerra	Warehouse Operator Operations
Deziree Leon	Janitor Operations	Erik Campos	Driver II
Dharmendra Prasad	Driver I	Erik Huynh	Warehouse Operator Operations
Diana Castanares	Warehouse Operator Operations	Erika Valladolid	Warehouse Operator Operations
Diana Hernandez	Warehouse Operator Operations	Ernesto Bautista	Driver II
Diana Joyce Bagang	Warehouse Operator Operations	Ernesto Hernandez [C]	Contingent Worker
Diana Perez	Maintenance Ld	Ernesto Zamora	Warehouse Ld Operations
Diana Pulido	Warehouse Ld Operations	Estella Wake	Trainer Branch
Diana Sanchez	Warehouse Operator Operations	Estrella Rosas	Warehouse Operator Operations
Diana Solis	Warehouse Operator Operations	Evangelina Villalpando Vargas (On Leave)	Delivery Driver
Diane Gandall	Training Coord Sr	Evelyn Estrada	Warehouse Operator Operations
Dianna Jasso	Warehouse Operator Operations	Evelyn Rosales	Inventory Coord Operations
Diego Guzman	Warehouse Operator Operations	Evencio Sanchez	Warehouse Operator Operations
Diego Torres-Escamilla	Warehouse Ld Operations	Everardo Rodriguez	Driver II
Dillan Vilayphone	Warehouse Ld Operations	Fabian Hernandez	Warehouse Operator Operations
Diron Robinson	Janitor Operations	Faith Gomez	Warehouse Operator Operations
Divontay Lebria	Delivery Driver	Farid Ahmed	Training Coord Sr
Dolores Jackson	Inventory Coord Operations	FAVIAN PEREZ	Warehouse Operator Operations
Dominic Castro	Warehouse Operator Operations	Felicia Mora	Warehouse Operator Operations
Don Flores	Warehouse Operator Operations	Feliciano Quismorio	Warehouse Operator Operations
Don Watari	Maintenance Ld	Fernanda Cabrera Hidalgo	Warehouse Operator Operations
Donald Hoeven	Driver II	Fernando Fragoso	Driver II
Donovan J Sandoval	Delivery Driver	Fiana Fleck	Inventory Coord Sr
Donoven McDonald	Warehouse Operator Operations	Fidencio Martinez	Warehouse Operator Operations
Doua Vue	Driver II	Fidencio Martinez	Warehouse Operator Operations
Douglas Hillian	Mgr Warehouse	Flint Mcculley	Driver II
Dwayne Butler	Warehouse Operator Operations	Francisco Melendrez (On Leave)	Warehouse Operator Operations
Dylan Ryan	Warehouse Operator Operations	Frank Elias	Driver II
Dylan Speed	Warehouse Operator Operations	Frank Hernandez	Trainer Branch
Edgar Fierros	Warehouse Operator Operations	Franklin Quintanilla	Warehouse Ld Operations
Edgar Vielma	Warehouse Operator Operations	Fuamatani Tagata	Warehouse Operator Operations
Edgardo Valenzuela Corrales	Supv Warehouse	Gabino Barreras	Warehouse Operator Operations
Eduardo Arroyo	Trainer Branch	Gabriel Sauceda	Warehouse Operator Operations
Eduardo Arteaga	Warehouse Operator Operations	Gabriela Pizano	Warehouse Operator Operations
Edwin Manalo	Warehouse Operator Operations	Gagandeep Grewal	Transportation Coord
Elena Castaneda (On Leave)	Warehouse Operator Operations	Gary Ernest	Driver II
Elijah Cuaderno	Warehouse Operator Operations	George Iniguez	Warehouse Operator Operations
Elizabeth Cardenas (On Leave)	Warehouse Operator Operations	Geovanni Anthonie Pedraza	Inventory Coord Operations
Elizabeth Ortiz	Warehouse Operator Operations	Gerard Capistrano	Warehouse Operator Operations
Elizabeth Perez	Warehouse Operator Operations	Gerson Villanueva Mendoza	Trainer Branch
Elizabeth Pono	Warehouse Operator Operations	Gilbert Escalante	Warehouse Ld Operations
Elvira Jimenez	Warehouse Operator Operations	Gilbert Falepouono	Warehouse Operator Operations
Emerson Matute (On Leave)	Warehouse Operator Operations	Gilman Falepouono	Warehouse Operator Operations
Emilen Santos	Warehouse Operator Operations	giselle contreras	Warehouse Operator Operations
Emilia Lopez	Warehouse Operator Operations	Glen Navarrete	Onsite Support Tech II
Emily Preston	Warehouse Operator Operations	Glenn Betanio	Warehouse Operator Operations
Emmanuel Soliven	Warehouse Operator Operations	Glenn Gaines	Driver II
Enrique Hernandez	Warehouse Operator Operations	Gregory Silas	Warehouse Operator Operations

Guillermo Cervantes Gutierrez	Warehouse Operator Operations	Javier Marquez	Warehouse Operator Operations
Gurmat Sidhu	Driver II	Javier Quintero	Warehouse Ld Operations
Gustavo Alvarado	Driver II	Javier Rios-Loza	Warehouse Operator Operations
Gustavo Sotomayor	Warehouse Operator Operations	Jay Villasista	Warehouse Operator Operations
Harmanpreet Singh	Warehouse Operator Operations	Jaymar Baclagan	Warehouse Ld Operations
Harry Paye	Warehouse Ld Operations	Jazmine Padron	Warehouse Operator Operations
Hazel Valdez	Warehouse Operator Operations	JEFFREY PIPPIN	Office Coord
Hector Arciniega	Warehouse Operator Operations	Jenee' Logette	Inventory Coord Operations
Hector Macias	Warehouse Operator Operations	Jennifer Cabrera Hidalgo	Warehouse Operator Operations
Hector Rodriguez	Warehouse Operator Operations	Jennifer Penaloza	Warehouse Operator Operations
Heerah Khan	Warehouse Clerk Operations	Jermaine Horton	Warehouse Operator Operations
Henry Macaraig	Warehouse Operator Operations	Jermel Fair	Warehouse Operator Operations
Hiyari Nakashima (On Leave)	Warehouse Operator Operations	Jerrell Leap	Driver II
Honorato Valdez	Warehouse Operator Operations	Jerryn Grundy	Warehouse Operator Operations
Hosanna Frausto Perez (On Leave)	Warehouse Operator Operations	Jesse Maciel	Warehouse Operator Operations
Hugo Rodriguez	Warehouse Operator Operations	Jesse Vargas	Warehouse Operator Operations
Isabella Polee	Warehouse Operator Operations	Jessica Madson	Warehouse Operator Operations
Isaiah Alberto	Warehouse Operator Operations	Jessie Alvarez	Warehouse Operator Operations
Ismael Felix	Warehouse Operator Operations	Jesus Barron	Warehouse Operator Operations
Ismael Rivera	Maintenance Tech II	Jesus Cazares	Warehouse Operator Operations
Issac Cuellar	Trainer Branch	Jesus Flores	Warehouse Operator Operations
Itzel Novoa	Warehouse Operator Operations	Jesus Garcia	Driver I
Ivan Thomas	Maintenance Tech I	Jesus Garcia	Warehouse Operator Operations
J Trinidad Fernandez	Warehouse Operator Operations	Jesus Hernandez	Warehouse Ld Operations
JACOB DE LA O	Warehouse Operator Operations	Jesus Lopez Diaz	Warehouse Operator Operations
Jacob Lopez	Warehouse Operator Operations	Jesus Rodriguez	Warehouse Operator Operations
Jacob Sabathia	Warehouse Operator Operations	Jesus Vargas [C]	Warehouse Operator
Jacqueline Cordova	Warehouse Ld Operations	Jesus Velazquez	Warehouse Operator Operations
Jacqueline Gmerek	Warehouse Operator Operations	Jinky Hansen	Quality Control Inspector II
Jacqueline Salgado	Warehouse Operator Operations	Joana Manjarrez	Warehouse Operator Operations
Jacquez Pough	Warehouse Operator Operations	Joanna Heng	Trainer Branch
Jaden Tanforan	Warehouse Operator Operations	Joaquin Ochoa	Warehouse Ld Operations
Jamaica Nelmida	Warehouse Operator Operations	Jobanpreet Singh	Warehouse Operator Operations
James Banks	Trainer Branch	Jocelyn Barajas	Warehouse Operator Operations
James Cardenas	Warehouse Operator Operations	Jodi Macdonald (On Leave)	Warehouse Operator Operations
James Dutter	Warehouse Operator Operations	Joe Correa	Warehouse Operator Operations
James Pierce	HR Generalist	Joe Devaughn	Driver II
James Turner	Sr Supv Warehouse	Joe Sountalavong	Driver II
James Woodard	Janitor Operations	Johan Calderon	Maintenance Tech I
Jamie Miller [C]	Warehouse Operator	John Morales	Warehouse Operator Operations
Jamie Wilcox	Warehouse Operator Operations	john padilla	Warehouse Operator Operations
Jamie Yang	Warehouse Operator Operations	John Valdez	Warehouse Operator Operations
Janelle Chavarria	Warehouse Ld Operations	Johnny Glover	Sr Dir Operations
Janet Presley	Warehouse Operator Operations	Johnny Talatham	Warehouse Operator Operations
Janeya Burton (On Leave)	Warehouse Operator Operations	Jonah Laguana	Warehouse Operator Operations
Jas Caceres	Warehouse Operator Operations	jonathan Arista Moreno	Warehouse Operator Operations
Jasmine Verdugo-Bonilla	Driver II	Jonathan Iddings	Warehouse Operator Operations
JASON MATIENZO	Warehouse Operator Operations	Jonathan Loayza	Warehouse Operator Operations
Jason Smith	Warehouse Operator Operations	Jonathan Phillip	Shuttle Driver
Jason Troie	Maintenance Tech II	Jonathan Rodriguez	Warehouse Operator Operations
Jaswinder Sandhu	Warehouse Operator Operations	Jordan Perez	Warehouse Operator Operations
Jaswinder Singh	Driver II	Jordan Sales	Warehouse Operator Operations
JAVIER GONZALEZ	Driver II	Jorge Baldiviezo Cruz	Warehouse Operator Operations

Jorge Paramo	Inventory Coord Sr	Kenny Leffle	Warehouse Operator Operations
Jory Hedgespeth	Warehouse Operator Operations	Kenzie Or Kenz Roybal	Janitor Operations
Josday Espinoza	Warehouse Clerk Operations	Keta Woodruff	Warehouse Operator Operations
Jose Avalos	Warehouse Operator Operations	Kevin Hang	Warehouse Operator Operations
Jose Faudoa	Warehouse Operator Operations	KEVIN SHOFNER	Warehouse Operator Operations
Jose Flores Reyes	Delivery Driver	KEVIN STERLING	Delivery Driver
Jose Martinez	Warehouse Operator Operations	Kevin Vidrio Caballero	Warehouse Operator Operations
Jose Mendoza	Trainer Branch	Kidd Sagapolutele	Warehouse Operator Operations
Jose Mendoza	Warehouse Operator Operations	Kimberly Rodriguez	HR Coord
Jose Ortiz	Driver II	Kimberly Tripplett	Warehouse Operator Operations
Jose Patague (On Leave)	Warehouse Operator Operations	Klarisse Vidal	Warehouse Operator Operations
Jose Perez	Driver II	Kolby Vidal	Inventory Coord Sr
Jose Perez	Warehouse Operator Operations	Kp Castanares	Warehouse Operator Operations
Jose Rodriguez	Warehouse Operator Operations	Kristian Villariba	Warehouse Operator Operations
Joseph De Anda	Warehouse Operator Operations	Kristina Miller	Supv Warehouse
Joseph Medina	Warehouse Operator Operations	Kyle Beasley	Warehouse Operator Operations
Joseph Rodriguez	Warehouse Operator Operations	Kyle Kaufmann	Maintenance Tech II
Joseph Sausau	Warehouse Operator Operations	Kyle Maria	Warehouse Operator Operations
Joseph Shackelford	Warehouse Operator Operations	Kyle Somerville	Warehouse Operator Operations
Joshua Jones	Driver II	Lady Marles	Warehouse Operator Operations
Joshua Pierceson	Maintenance Tech I	Lamar Smith	Warehouse Operator Operations
Joshua Rheinor	Warehouse Ld Operations	Laura Garcia	Supv Warehouse
Josue Castro Mayotquin [C]	Driver II	Laura Rivas	Warehouse Operator Operations
Jovito Limbag	Driver I	Leah Mcrae	Warehouse Operator Operations
Jozy Moreno	Dispatcher	Leo Beltran	Warehouse Operator Operations
Juan Ambriz Zarco	Warehouse Operator Operations	Leonard Vargas	Warehouse Operator Operations
Juan Arreola	Warehouse Operator Operations	Leonardo Cervantes	Warehouse Operator Operations
JUAN HERNANDEZ	Warehouse Operator Operations	Leonardo Miranda	Warehouse Operator Operations
Juan Martinez	Warehouse Operator Operations	Leslie Saborrido	Warehouse Operator Operations
Juan Olmos	Warehouse Operator Operations	Lesly Sanchez	Warehouse Operator Operations
Juan Resendiz	Shuttle Driver	Leticia Mora	Warehouse Operator Operations
Judith Limon	Trainer Branch	Lidia Cortez	Warehouse Operator Operations
Julian Eduardo Bravo Lemus	Inventory Coord Sr	Lilia Vega	Warehouse Operator Operations
Junie Argoncillo	Warehouse Operator Operations	Lilianna Vasquez	Warehouse Ld Operations
JUNIUS PARAS	Warehouse Operator Operations	Lillian Azuara	Warehouse Operator Operations
Justin Johnson	Warehouse Operator Operations	Lizeth Cuellar Ramos	Quality Control Inspector II
Justin San Gabriel	Trainer Branch	Lizzeth Millan Ojeda	Warehouse Operator Operations
Justina Leng	Warehouse Operator Operations	Lorenzo Jimenez	Regional Fleet Maintenance Manager
Justine Bagang	Trainer Branch	Lori Dionne	Supv Warehouse
Kaileah Johannsen	Warehouse Operator Operations	Lorina Caroro	Warehouse Operator Operations
Kaitlyn Sheehy	Warehouse Ld Operations	Louie Miranda	Warehouse Operator Operations
Kamach Ork	Warehouse Operator Operations	Lourdes Vences	Warehouse Operator Operations
Kameron White	Mgr Warehouse	Lucas Javier Caroro	Warehouse Operator Operations
Kanisha Bennamon	Warehouse Operator Operations	Luis Afanador	Warehouse Operator Operations
Kao Saelee	Trainer Branch	Luis Mora Garcia	Warehouse Operator Operations
Karen Suarez paz	Warehouse Operator Operations	Luis Ventura	Warehouse Operator Operations
Karen Werner	Warehouse Clerk Operations	Lupe Patterson	Warehouse Clerk Operations
Karina Cruz	Supv Warehouse	Lyn Bowker	Warehouse Operator Operations
Katrina Hernandez	Warehouse Operator Operations	Lynn Mcqueen	Warehouse Operator Operations
Katrina Sanchez	Warehouse Operator Operations	Makeda Word	Sr Mgr HR
Kayla Whitaker Davis	Warehouse Operator Operations	Makiayla Smith	Warehouse Clerk Operations
Keila Gastelum	Warehouse Operator Operations	Malaika Donelson	Warehouse Operator Operations
Kelly Dornbush	Driver II	Malivanh Vilayphone	Warehouse Operator Operations
Kendell Lewis	Warehouse Operator Operations	Maninder Kaur	Warehouse Operator Operations

Manolo Reyes	Warehouse Operator Operations
Manuel Antuna	Driver II
Marc Padilla	Warehouse Operator Operations
Marc Richie	Warehouse Operator Operations
Marcos Cabrera	Warehouse Operator Operations
Marcus Balatayo	Janitor Operations
Marcus Brown	Warehouse Operator Operations
Marcus Garcia	Warehouse Operator Operations
Maria A Leon	Driver I
Maria Alonso	Warehouse Operator Operations
Maria Edith Mata Mejia	Warehouse Operator Operations
Maria Garcia	Warehouse Operator Operations
MARIA LEMUS	Warehouse Operator Operations
Maria Montanez-Vazquez	Supv Warehouse
Maria Romero	Driver II
Maria Servin	Warehouse Ld Operations
Maria Zargi	Warehouse Operator Operations
Maricela Ocampo Diaz	Janitor Operations
Marie Poutous	Warehouse Operator Operations
Mariela Moreno	Warehouse Operator Operations
Marietta Tanqueco	Warehouse Operator Operations
Mario Delgado	Warehouse Operator Operations
Mario Espinosa [C]	Warehouse Operator
Mario Nazareno	Driver II
Mario Sierra Suarez	Warehouse Operator Operations
Marisela Gallardo	Inventory Coord Operations
Marissa Allen	Warehouse Operator Operations
Marissa Monjes	Warehouse Operator Operations
Maritza Villalobos	Warehouse Operator Operations
Mark Delisle	Warehouse Operator Operations
Mark Marcos	Warehouse Operator Operations
Mark Nicolas	Warehouse Operator Operations
Mark Sabandal	Warehouse Operator Operations
Marleena Ytuarte	Janitor Operations
Martha Perez	Warehouse Operator Operations
Martha Villasenor	Warehouse Operator Operations
Martin Angulo	Warehouse Operator Operations
Martin Valencia	Driver II
Marvin John Tela	Warehouse Operator Operations
Matthew Rocha	Warehouse Operator Operations
Matthew Villasana	Warehouse Operator Operations
Maureen Formoso	Warehouse Operator Operations
Maximiliano Herrera	Warehouse Operator Operations
Maya Khan (On Leave)	Warehouse Operator Operations
Mehnaaz Khan	Warehouse Operator Operations
Melinda Meza	Driver II
Melissa Monjes	Inventory Coord Operations
Meredith Jaquias	Janitor Operations
Michael Crow	Warehouse Operator Operations
Michael Escobar	Warehouse Ld Operations
Michael Harder	Warehouse Operator Operations
Michael Morgan	Sr Mgr Operations
Michael Racanelli	Warehouse Operator Operations
Michael Santos	Warehouse Operator Operations
Michael Williamson	Warehouse Operator Operations
Michelle Penaloza	Warehouse Operator Operations
Michelle Rangel Magana [C]	Driver II
Miguel Mata	Warehouse Operator Operations
Miguel Velazquez Andrade	Warehouse Operator Operations
Mikey Turner	Warehouse Operator Operations
Mina Diaz	Warehouse Operator Operations
Miranda Mejia	Warehouse Operator Operations
Miriam Limas	Warehouse Operator Operations
Misael Acosta	Warehouse Operator Operations
Miuriel Quant	Inventory Coord Operations
Mohamad Soboh	Warehouse Operator Operations
Mohammed Ashaf	Warehouse Operator Operations
Mohammed Olomari	Warehouse Operator Operations
Moimoi Ponitini	Supv Warehouse
Molly Siv	Warehouse Operator Operations
Monica Alarcon Roque	Warehouse Operator Operations
Monique Damiano	Warehouse Operator Operations
Moua Vang	Driver II
NANCY LOPEZ	Warehouse Operator Operations
Narinder Pal Kaur	Warehouse Operator Operations
Natalie Ramirez	Warehouse Operator Operations
Nate Dinkins	Warehouse Operator Operations
Nate Galvan	Warehouse Operator Operations
Nathaniel Navarrete	Warehouse Operator Operations
Nerie Joya	Janitor Operations
Nicholas Messier	Warehouse Operator Operations
Nicholas Silva	Warehouse Operator Operations
Nick Appleby	Driver II
Nick Giron	Supv MedTrans
Nico Mesina	Onsite Support Tech II
Nicole Vargas	Warehouse Operator Operations
Niyah Rangel	Warehouse Operator Operations
Noel Pangaliman	Warehouse Operator Operations
Noemielind Andrade	Warehouse Operator Operations
Noeun Grandy	Warehouse Operator Operations
Nora Morelos	Warehouse Operator Operations
Nyeem Green	Warehouse Operator Operations
Omar Bermudez	Warehouse Operator Operations
Omar Guro	Warehouse Operator Operations
Omar Lopez	Warehouse Operator Operations
Omariyon Wilson	Warehouse Operator Operations
Oneal Bracken	Janitor Operations
Orlando Lua	Maintenance Tech II
Osbaldo Saravia	Warehouse Operator Operations
Oscar Baron	Warehouse Operator Operations
Oscar Torres	Maintenance Tech I
Paola Hernandez	Warehouse Operator Operations
Paramjit Boparai	Warehouse Operator Operations
Paramjit Kaur	Warehouse Operator Operations
Parimal Pingale	Engineer Process
Patricia Patague	Warehouse Operator Operations
Patricia Rios	Warehouse Operator Operations
Patricia Sandoval	Inventory Control Ld Operations

Paul Cardenas	Warehouse Clerk Operations	Rikkilee Fagundes	Supv Warehouse
Paviter Singh	Driver II	Robert Black	Warehouse Operator Operations
Pawanjot Kaur	Warehouse Clerk Operations	Robert Cancilla	Warehouse Operator Operations
Pawanpreet Chandi	Warehouse Operator Operations	Robert Cervantez	Driver II
Pearun Kong	Maintenance Tech II	Robert Dabbs	Driver II
Pedro Jimenez JR	Warehouse Operator Operations	Robert Gamboa	Warehouse Operator Operations
Peter Chavez	Warehouse Operator Operations	Robert Heifner	Warehouse Operator Operations
Peter Chu	Mgr MedTrans	Robert Herrera	Supv Warehouse
Peter Mendez	Warehouse Operator Operations	Robert Oino	Supv MedTrans
Phillipe Carlon	Warehouse Operator Operations	Robert Schupp (On Leave)	Driver II
phirum phin	Warehouse Operator Operations	Roberto Ordaz-Morales	Driver II
Phonexay Phommachak (On Leave)	Driver II	Rodney Tober	Driver II
PORFIRIO ARMAS	Warehouse Operator Operations	Romeil Jones [C]	Contingent Worker
Preslyn Hernandez	Trainer Branch	Rommel Reside	Inventory Coord Operations
Rabee Bonjoc	Warehouse Operator Operations	Ronald Noun	Warehouse Operator Operations
Rafael Carranza	Warehouse Operator Operations	Rony Arauz	Maintenance Tech II
Rafael De La Cruz	Warehouse Operator Operations	Rosa Carmina Torres Ulloa	Inventory Coord Operations
Rafael Sosa Rodriguez (On Leave)	Delivery Driver	Rosario Gonzalez Campos	Janitor Operations
Raja Ahmed	Driver Ld	Rosie Reza	Warehouse Operator Operations
Rajdeep Hira	Warehouse Operator Operations	Rowell Aguilar	Warehouse Operator Operations
Rajinder Kaur	Transportation Coord	Rowell Gali	Supv Maintenance
Rajveer Sidhu	Warehouse Operator Operations	Ruben Arellano	Warehouse Operator Operations
Rajvir Chahal	Warehouse Operator Operations	Ruben Carrasquel Lira	Warehouse Operator Operations
Ramon Gonzales	Delivery Driver	Ruben Romero	Warehouse Operator Operations
Randy Carter	Delivery Driver	Rubia Romero Reyes	Warehouse Operator Operations
randy ogana	Delivery Driver	Rudy Pena	Sr Mgr Operations
Ranniel Aranas	Warehouse Operator Operations	Rusana Agdeppa	Warehouse Operator Operations
Raquel Torres	Trainer Branch	Ryan Gonzales	Warehouse Operator Operations
Ratana Lath	Warehouse Ld Operations	Ryan Martinez	Trainer Branch
Raul Gutierrez	Warehouse Operator Operations	Sabrina Seuell	Warehouse Clerk Operations
Raul Sixtos	Warehouse Ld Operations	Sacarias Ramirez Buenrostro	Driver II
Raul Tello	Trainer Branch	Sadiq Mohammed	Driver I
Ray Garrett	Warehouse Operator Operations	Sadol Osorio	Warehouse Operator Operations
Ray Ray Hernandez	Warehouse Operator Operations	Saiyad Akhtar	Warehouse Ld Operations
RAY UIA	Warehouse Operator Operations	Saiyad Ashik	Janitor Operations
Raymond De Vera	Inventory Coord Operations	Salvador Canela-Gonzalez	Warehouse Operator Operations
Raymond Rodriguez	Warehouse Operator Operations	Saman Sao	Warehouse Operator Operations
Reggie Ricks	Driver II	Sammy Biado	Warehouse Operator Operations
Remy Cortes	Warehouse Operator Operations	Samuel Cardenas	Warehouse Operator Operations
Renee Marroquin	Warehouse Operator Operations	Samuel Solorzano	Warehouse Ld Operations
Reno Garcia (On Leave)	Warehouse Operator Operations	Sandra Vazquez	Warehouse Ld Operations
RENZO DULAY	Warehouse Operator Operations	Sandy Maya	Warehouse Operator Operations
Reyanna Wright	Warehouse Operator Operations	Sarah Potter	Training Coord Sr
Reynol Celestino Mata [C]	Driver II	Sarai Castillo	Warehouse Operator Operations
Rhea Llanes	Warehouse Operator Operations	Saray Valdes	Warehouse Operator Operations
Ricardo Carranza	Delivery Driver	Satwinder Singh	Warehouse Operator Operations
Ricardo Marquez	Warehouse Ld Operations	Saul Alvizar	Warehouse Operator Operations
Ricardo Velasquez	Warehouse Operator Operations	Saul Larios	Warehouse Operator Operations
Richard Arretche	Sr Mgr Medtrans	Sebastian Marquez	Warehouse Operator Operations
Richard Ramos	Warehouse Operator Operations	Seema Rani	Warehouse Operator Operations
Ricky James	Warehouse Operator Operations	Seng Xiong	Driver II
Ricky Richard	Warehouse Operator Operations	Serafin Garcia	Warehouse Operator Operations
Rigoverto Garcia Valadez	Warehouse Operator Operations	Serhii Tabakar	Warehouse Operator Operations

Seth Sanchez-Claffey	Supv Warehouse
Sharan Sandhu	Warehouse Operator Operations
Shelby Lopez	Janitor Operations
Sherraine Lewis	Warehouse Operator Operations
Shiloh Tillery	Warehouse Operator Operations
Shinderpal Kaur	Warehouse Operator Operations
Skye Leal	Warehouse Operator Operations
Somnang chea	Warehouse Operator Operations
Somontha Mam	Inventory Coord Operations
Sonia Chavez	Warehouse Operator Operations
Soung Sim	Driver II
Stanley Anguiano	Quality Control Inspector I
Starlett Silva	Warehouse Operator Operations
Steevi Lopez	Warehouse Operator Operations
Stephanie Arroyo Valentin (On Leave)	Warehouse Operator Operations
Stephanie Bellido (On Leave)	Warehouse Operator Operations
Stephanie Carrillo Gonzalez	Warehouse Operator Operations
Stephen Barbosa	Warehouse Operator Operations
Stina Arreaga	Warehouse Operator Operations
Suneetha Debbad	Warehouse Operator Operations
sylvia broderick	Warehouse Operator Operations
Tamara Thomas	Warehouse Operator Operations
Tamika Noble	Warehouse Operator Operations
Tammy Evans	Driver II
Tammy Wade	Warehouse Operator Operations
Tanisha Shoemaker	Warehouse Operator Operations
Tataneshia Parker	Warehouse Operator Operations
Tawny Powell	Delivery Driver
Teodoro Urena	Warehouse Operator Operations
Teresa Henry	Supv Warehouse
Teresa Ogle	Warehouse Ld Operations
Terrell Gibson	Warehouse Operator Operations
Terrence Chua	Warehouse Operator Operations
Tevin Davis	Warehouse Operator Operations
Theo Sountalavong	Warehouse Operator Operations
Thomas Cooney	Warehouse Operator Operations
Thomas White	Warehouse Operator Operations
Timothy Goodman	Driver I
TIMOTHY TORRES	Warehouse Operator Operations
Tina Ayers	Supv Inventory Control
Todd Felis	Warehouse Operator Operations
Tom Castro	Driver II
Tony Costa	Dir Maintenance
Tony Marquez	Warehouse Ld Operations
Tracy Estrada	Warehouse Operator Operations
Trejon Anthony - Jackson (On Leave)	Warehouse Operator Operations
Troy Collins	Warehouse Operator Operations
TROY MULLEN (On Leave)	Warehouse Operator Operations
Tuku Ashera	Warehouse Operator Operations
Tyler Wachtel	Warehouse Ld Operations
Tyrone Tanner	Warehouse Operator Operations
Valarie Price	Warehouse Operator Operations
Valentino Martinez	Warehouse Operator Operations
Vanessa Saldivar	Warehouse Clerk Operations
Veera Venkata Rayudu	Warehouse Operator Operations
Venisha Bailey	Warehouse Operator Operations
Vernard Bailey	Warehouse Ld Operations
Veronica Osorio	Warehouse Operator Operations
Veronica Romero	Driver II
Vi-Berly Fregillana	Inventory Control Ld Operations
Vicky Gailey	Inventory Coord Operations
Victor Nerecina	Warehouse Operator Operations
Victor Vazquez	Driver II
Victoria Garcia	Warehouse Ld Operations
Vincent Tanega	Warehouse Ld Operations
Violet Velasquez-Pedroza	Warehouse Operator Operations
Viridiana Espinoza	Warehouse Operator Operations
Weston Hogle	Warehouse Operator Operations
Will Sobarzo	Warehouse Operator Operations
William Fenton	Warehouse Ld Operations
Yadira Maldonado (On Leave)	Warehouse Operator Operations
Yansamnan Kong	Supv Warehouse
Yasmin Afanador	Warehouse Operator Operations
Yasmin Nehar	HR Generalist
Yasmine Garces	Warehouse Operator Operations
Yesenia Gonzalez	Warehouse Operator Operations
Yesenia Pacheco	Warehouse Operator Operations
Yolanda Arenas	Warehouse Ld Operations
YOLANDA NAVA	Transportation Coord
Ysabella Romasanta	Warehouse Operator Operations
Yuritzi Chavez	Warehouse Operator Operations
Yvonne Kemp	Warehouse Operator Operations
Zachary Smith	Warehouse Operator Operations
Zaida Arzate	Warehouse Operator Operations
Zaki Nizam	Janitor Operations
Zayvian Manriquez	Warehouse Operator Operations
Zeke Markham	Warehouse Operator Operations
Zenaphan Ward	Inventory Coord Sr

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 001-43022

Medline Inc.

(Exact name of registrant as specified in its charter)

Delaware	**33-1845288**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3 Lakes Drive Northfield, Illinois	**60093**
(Address of principal executive offices)	(Zip Code)

(847) 949 5500
Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, par value $0.0001 per share	MDLN	Nasdaq Global Select Market

Securities registered pursuant to section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☐ No ☒

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ☐ No ☒

The aggregate market value of the Class A common stock held by non-affiliates of the registrant, based on the closing price of a share of Class A common stock on December 17, 2025, as reported by The Nasdaq Global Select Market on such date was approximately $13.0 billion. The registrant has elected to use December 17, 2025, which was the initial trading date of the registrant's Class A common stock on The Nasdaq Global Select Market, as the calculation date because on June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter) the registrant was a privately held company. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of February 23, 2026, there were 811,647,534 shares of the registrant's Class A common stock and 502,045,878 shares of the registrant's Class B common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement related to its 2026 Annual Meeting of Stockholders to be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year ended December 31, 2025 are incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

Item		Page
	PART I	
1.	Business	7
1A.	Risk Factors	22
1B.	Unresolved Staff Comments	55
1C.	Cybersecurity	55
2.	Properties	56
3.	Legal Proceedings	56
4.	Mine Safety Disclosures	57
	PART II	
5.	Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities	58
6.	[Reserved]	60
7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	61
7A.	Quantitative and Qualitative Disclosures About Market Risk	78
8.	Financial Statements and Supplementary Data	80
9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	135
9A.	Controls and Procedures	135
9B.	Other Information	135
9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	136
	PART III	
10.	Directors, Executive Officers, and Corporate Governance	136
11.	Executive Compensation	136
12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	136
13.	Certain Relationships and Related Transactions, and Director Independence	136
14.	Principal Accountant Fees and Services	136
	PART IV	
15.	Exhibits and Financial Statement Schedule	137
16.	Form 10-K Summary	142
	Signatures	143

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements include all statements that are not historical facts. Words such as "anticipate," "assume," "believe" "contemplate," "continue," "could," "estimate," "expect," "foreseeable," "intend," "may," "plan," "potentially," "predict," "project," "seek," "should," "will," or "would," or similar words or phrases that convey uncertainty of future events or outcomes, are intended to identify forward-looking statements in this Annual Report. These forward-looking statements relate to matters such as our industry, business strategy, costs, and costs savings, impacts of accounting standards and guidance, goals and expectations, market position, future operations, margins, profitability, capital expenditures, liquidity and capital resources, legal matters, trends, and other financial and operating information. The forward-looking statements are based on management's current expectations and are subject to various risks, uncertainty, and changes in circumstances, many of which are beyond our control, that could cause actual results to differ materially. Although we believe that the assumptions underlying the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance, or achievements. Factors that may cause actual results to differ from expected results include those described in Part I, "Item 1A—Risk Factors" and Part II, "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations". The forward-looking statements included in this Annual Report speak only as of the date of this Annual Report or as of the date they are made, as applicable. Except as otherwise required by law, we disclaim any intent or obligation to update any "forward-looking statement" made in this Annual Report to reflect changed assumptions, the occurrence of unanticipated events, or changes to future operating results over time.

INTRODUCTORY NOTE

Medline Inc. was incorporated as a Delaware corporation on November 6, 2024. Prior to the completion of its initial public offering (the "IPO") on December 18, 2025, Medline Inc. undertook certain reorganization transactions (the "Reorganization") such that Medline Inc. is now a holding company, and its sole material assets are its equity interests held directly or indirectly through wholly owned subsidiaries in Medline Holdings, LP ("Medline Holdings"). Following the IPO, Medline Holdings is the predecessor of Medline Inc. for financial reporting purposes. As the general partner of Medline Holdings, Medline Inc. now operates and controls all of the business and affairs of Medline Holdings and, through Medline Holdings and its subsidiaries, conducts its business. The Reorganization lacks economic substance and therefore is accounted for in a manner consistent with a reorganization of entities under common control. As a result, the consolidated financial statements of Medline Inc. recognize the assets and liabilities received in the Reorganization at their historical carrying amounts, as reflected in the historical financial statements of Medline Holdings. Medline Inc. will consolidate Medline Holdings on its consolidated financial statements and record a non-controlling interest related to the Units (as defined herein) held by the Continuing Unitholders (as defined herein) on its consolidated balance sheets and statements of comprehensive income.

Medline Inc. had no significant business transactions or activities prior to the Reorganization, and, as a result, the historical financial information reflects that of Medline Holdings.

Basis of Presentation

The consolidated financial statements and accompanying notes included herein are prepared in accordance with United States generally accepted accounting principles ("GAAP"). The results of businesses acquired or disposed of are included in the consolidated financial statements from the date of the acquisition or up to the date of disposal, respectively. All adjustments, in the opinion of management, necessary to a fair statement of the results for the annual periods presented have been made.

Certain monetary amounts, percentages, and other figures included in this Annual Report have been subject to rounding adjustments. Percentage amounts included in this Annual Report have been calculated, in some cases, not on the basis of such rounded figures, but on the basis of such amounts prior to rounding. For this reason, percentage amounts in this Annual Report may vary from those obtained by performing the same calculations using the figures, on the face of our consolidated financial statements included elsewhere in this Annual Report. Certain other amounts that appear in this Annual Report may not sum due to rounding.

In December 2024, we changed the name of Medline Holdings from Mozart Holdings, LP to Medline Holdings, LP. We will not distinguish between the prior and current name of Medline Holdings and will refer to the current name of Medline Holdings throughout this Annual Report. References in this Annual Report to "Medline," the "Company," "we," "us," and "our" refer (1) prior to the consummation of the IPO, to Medline Holdings, LP and its consolidated subsidiaries and (2) after the IPO to Medline Inc. and its consolidated subsidiaries.

CERTAIN DEFINITIONS

As used in this Annual Report, unless otherwise noted or the context requires otherwise, the following terms have the following meanings:

- "Class A Units" refers to the interests in Medline Holdings called "Class A Units" that were outstanding prior to the Reclassification. In connection with the Reclassification, (i) Class A Units held by Common Unitholders were converted into Common Units and (ii) Class A Units held by Exchanging Class A Unitholders were directly or indirectly exchanged for shares of Class A common stock.
- "Class B Units" refers to the interests in Medline Holdings called "Class B Units" that were outstanding prior to the Reclassification, and does not include CUPI Units. In connection with the Reclassification, (i) Class B Units held by Incentive Unitholders were converted into Incentive Units and (ii) Class B Units held by Exchanging Class B Unitholders were directly or indirectly exchanged for shares of Class A common stock (in the case of vested Class B Units) and/or restricted shares of Class A common stock (in the case of unvested Class B Units).

- "Common Units" refers to the new class of units of Medline Holdings created by the Reclassification and does not include Incentive Units.
- "Common Unitholders" refers to certain pre-IPO holders of Class A Units and/or CUPI Units who hold Common Units following the Reclassification.
- "Incentive Unitholders" refers to certain pre-IPO holders of Class B Units who will hold Incentive Units following the Reclassification, as described under "Organizational Structure."
- "Continuing Unitholders" refers collectively to Common Unitholders and Incentive Unitholders.
- "CUPI Units" refers to the interests in Medline Holdings that were designated as "Catch-Up Class B Units" and outstanding prior to the Reclassification. In connection with the Reclassification, (i) CUPI Units held by Common Unitholders were converted into Common Units and (ii) CUPI Units held by Exchanging CUPI Unitholders were directly or indirectly exchanged for shares of Class A common stock.
- "Designating Stockholder" refers to each of our Principal Stockholders with whom we entered into separate director nomination agreements.
- "Exchanging Class A Unitholder" refers to pre-IPO holders of Class A Units whose Class A Units were directly or indirectly exchanged for shares of Class A common stock following the Reclassification.
- "Exchanging Class B Unitholder" refers to pre-IPO holders of Class B Units whose Class B Units were directly or indirectly exchanged for shares of Class A common stock (in the case of vested Class B Units) and/or restricted shares of Class A common stock (in the case of unvested Class B Units) following the Reclassification.
- "Exchanging CUPI Unitholder" refers to pre-IPO holders of CUPI Units whose CUPI Units were directly or indirectly exchanged for shares of Class A common stock following the Reclassification.
- "Exchanging Unitholders" refers collectively to Exchanging Class A Unitholders, Exchanging CUPI Unitholders, and Exchanging Class B Unitholders.
- "Incentive Units" refers to the new class of units of Medline Holdings created by the reclassification of the Class B Units in the Reclassification. The Incentive Units are "profit interests" having economic characteristics similar to stock appreciation rights and having the right to share in any equity value of Medline Holdings above specified participation thresholds. Vested Incentive Units may be converted to Common Units and be subsequently exchanged for shares of Class A common stock.
- "Principal Stockholders" refers collectively to investment funds associated with Blackstone Inc., The Carlyle Group Inc. and Hellman & Friedman LLC, and members of the Mills family.
- "Reclassification" refers to the reclassification of the partnership interests of Medline Holdings prior to the IPO.
- "Sponsors" refers collectively to Blackstone Inc., The Carlyle Group Inc., and Hellman & Friedman LLC.
- "Units" refers collectively to Common Units and Incentive Units.

Summary of Risk Factors

The following is a summary of the principal factors that make an investment in our securities speculative or risky, all of which are more fully described below. This summary should be read together with the risk factors described under Part I, "Item 1A—Risk Factors" and should not be relied upon as an exhaustive summary of the material risks facing our business. In addition to the following summary, you should consider the information set forth below and the other information contained in this Annual Report before investing in our securities.

- Our global operations are subject to inherent risks that could materially adversely affect our business, results of operations, and financial condition.
- We may be unable to derive fully the anticipated benefits from our existing or future acquisitions, joint ventures, investments, dispositions, or other strategic transactions.
- Consolidation in the healthcare industry could have an adverse effect on our business, results of operations, and financial condition.
- We operate in a highly competitive industry, with accelerating pricing pressure and changes in technology.
- Changes to the U.S. and global healthcare environments may not be favorable to us.
- Increases in shipping costs or service issues with our third-party shippers could harm our business.

- Significant challenges or delays in our sourcing of new products and technologies could have an adverse impact on our long-term success.
- We have concentration in and dependence on certain healthcare provider customers and GPOs.
- Our business and operations depend on the proper functioning of our critical facilities and distribution networks and could be negatively impacted by events outside our control.
- Quality problems and product liability claims have in the past led, and could in the future lead, to recalls or safety alerts, reputational harm, adverse verdicts, or costly settlements, and could have a material adverse effect on our business, results of operations, and financial condition.
- Our failure to establish and maintain Prime Vendor relationships may cause our revenue to decline.
- If we experience increased pressure to maintain or decrease the price of our goods and services and we are unable to reduce our expenses, there may be a material adverse effect on our business, results of operations, and financial condition.
- Any failure by or loss of a third-party manufacturer or supplier or other manufacturing or supply-related impacts could result in delays and increased costs, which may adversely affect our business.
- We rely on the proper function, security, and availability of our information technology systems and data, as well as those of third parties throughout our global supply chain, to operate our business.
- We are subject to extensive and complex laws and governmental regulations and any adverse regulatory action may materially adversely affect our business, results of operations, and financial condition both inside and outside the United States.
- We are subject to complex and rapidly evolving data privacy, security, and data protection laws and regulations and the costs to comply with such laws and regulations or any ineffective compliance efforts with such laws and regulations may adversely impact our business.
- Our use or our third-party service providers' or business partners' use of AI, automated decision-making and machine learning technologies and the evolving regulatory framework in this area may subject us to risks or heightened costs that could adversely affect business, results of operation and financial condition.
- Our failure to comply with laws and regulations relating to reimbursement of healthcare goods and services may subject us to penalties and adversely impact our reputation, business, results of operations, financial condition, and cash flows.
- Uncertain global and domestic macro-economic and political conditions could materially adversely affect our business, results of operations, and financial condition.
- Our substantial indebtedness could adversely affect our financial condition, our ability to operate our business or react to changes in the economy or our industry, prevent us from fulfilling our obligations under our debts, and divert our cash flow from operations for debt payments.
- The credit agreement that governs the Senior Secured Credit Facilities and the indentures that govern the Senior Notes will each impose significant operating and financial restrictions on our subsidiaries, which may prevent us from capitalizing on business opportunities.
- Medline Inc. is a holding company and its only material assets are its equity interests held directly or indirectly through wholly owned subsidiaries in Medline Holdings, and it is accordingly dependent upon distributions from Medline Holdings to pay taxes, make payments under the tax receivable agreement, and pay any dividends.
- The Designating Stockholders hold a significant percentage of our stock, and their interests may conflict with ours or yours in the future.
- Our amended and restated certificate of incorporation does not limit the ability of our Sponsors, the Mills family, and certain other pre-IPO investors to compete with us, and they may have investments in businesses whose interests conflict with ours.

The market price of shares of our Class A common stock may be volatile or may decline regardless of our operating performance, which could cause the value of your investment to decline.

Market and Industry Data

Unless otherwise indicated, information contained in this Annual Report concerning our industry, competitive position, and the markets in which we operate is based on information from independent industry and research organizations, other third-party sources and management estimates. Although we believe that these third-party sources are reliable, we do not guarantee the accuracy or completeness of this information, and we have not independently verified this information. Management estimates are derived from information obtained from surveys, reports by market research firms, our customers, distributors, suppliers, trade and business organizations, and other contacts in the markets in which we operate and have not been verified by independent sources, and are based on assumptions made by us upon reviewing such data, and our experience in, and knowledge of, such industry and markets, which we believe to be reasonable. In addition, assumptions and estimates of our and our industry's future performance are subject to a high degree of uncertainty and risk due to a variety of factors, including those described in Part I, "Item 1A—Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

Statements regarding our market position (including statements that we are the largest company in a particular market), unless otherwise noted, are based on our 2025 net sales in the relevant market relative to the publicly reported net sales of our competitors in such market, including with respect to our statement of being the largest provider of med-surg products and supply chain solutions serving all points of care, as that statement is based on our 2025 net sales relative to the publicly reported net sales of med-surg products by companies that are both med-surg manufacturers and distributors.

Trademarks

We own or have the right to use trademarks, trade names, and service marks used in connection with our business, including, but not limited to, Medline, Curad, Microtek, Hudson, and Proxima. All trademarks, trade names, and service marks referred to in this Annual Report are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks, or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies. Solely for convenience, our trademarks, trade names, and service marks referred to in this Annual Report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names, and service marks.

PART I

Item 1. Business

General

Medline Inc. (together with its subsidiaries, "Medline", "the Company", "we", "ours" and "us") is the largest provider of medical-surgical ("med-surg") products and supply chain solutions serving all points of care, based on total net sales of med-surg products. Medline was founded in 1966 and today delivers mission-critical products used daily across the full range of care settings, from hospitals and surgery centers to physician offices and post-acute facilities. Our mission is to make healthcare run better by delivering improved clinical, financial, and operational outcomes.

We have two reportable segments, Medline Brand and Supply Chain Solutions, the combination of which addresses critical needs in the market through a comprehensive solution. They are both supported by our Prime Vendor model, differentiated distribution network, and robust commercial platform. Through our two segments, we offer approximately 335,000 med-surg products, including surgical and procedural kits, gloves and protective apparel, urological and incontinence care, wound care, and consumable lab and diagnostics products. We distribute these products through our expansive network of global distribution facilities and our owned fleet of MedTrans trucks.

Medline Brand

As of December 31, 2025, we offer our customers approximately 190,000 med-surg products through our Medline Brand segment and hold leading positions across many key product families for our Medline Brand products. Our Medline Brand products are organized into three product categories: Front Line Care, Surgical Solutions, and Laboratory and Diagnostics.

- *Front Line Care* offers mission-critical med-surg products for patient-facing needs, including wound care products, exam gloves, skin care and incontinence products, environment cleaning supplies, textiles, hand sanitizer, durable medical equipment, patient plastics, and decolonization and infection control products.
- *Surgical Solutions* offers operating room and perioperative environment product solutions, including surgical procedure trays, drapes and gowns, personal protective equipment, sterile wraps, surgical instruments, surgeon's gloves, procedure kits, and orthopedic implants.
- *Laboratory and Diagnostics* offers a full range of laboratory and diagnostic product solutions, including point of care testing, analyzers and instrumentation, lab and diagnostic consumables, diagnostic instruments, vital signs monitors, and anatomic pathology and phlebotomy products.

Our product development approach incorporates customer feedback and ongoing innovation. We are also committed to delivering products of the highest standard, which is reflected by our robust quality team embedded across our manufacturing and sourcing locations. The expertise of our research and development team and quality team helps ensure products bearing the Medline brand meet both our rigorous quality standards and our customers' expectations.

Supply Chain Solutions

As of December 31, 2025, we offer approximately 145,000 med-surg products from over 1,300 third-party suppliers, including nearly all leading national brands, through our Supply Chain Solutions segment. We also provide our customers with supply chain optimization services such as consulting engagements, outsourced warehouse and technology management, put-away-ready packaging, third-party logistics, inventory rationalization, and route planning. Our third-party suppliers are primarily responsible for costs related to import and inbound freight, whereas we are primarily responsible for costs related to outbound freight from our distribution centers. Our supply chain expertise allows us to provide additional service offerings to optimize our customers' supply chain and inventory workflows, helping these customers cost-effectively manage their supply chain while building strong relationships and enhancing retention.

0810

Our Prime Vendor Model

A Prime Vendor relationship is a relationship for which there is a multi-year distribution agreement between Medline and a customer, whereby the customer agrees to use Medline for the vast majority of its med-surg product needs.

In our Prime Vendor relationships, we enter into long-term agreements, typically structured with five-year terms, to act as the primary consolidated logistics partner for these customers' med-surg product needs. These agreements have been and are expected to continue to be a key contributor to our growth. Our customers realize efficiencies by partnering with one supply chain partner to consolidate their med-surg purchase volume. Prior to the market adoption of the Prime Vendor model, customers sourced such products individually from a highly fragmented base of suppliers. The Prime Vendor model instead centralizes procurement and distribution, which in turn drives efficiency and higher service levels.

As Prime Vendor, we drive significant cost savings to our customers. Our scale allows us to deliver consistently lower prices and better service levels on Medline Brand products relative to third-party alternatives, while also lowering the distribution cost for delivery of the full range of med-surg products. This often motivates customers to purchase more Medline Brand products over time. The opportunity is even greater in certain non-acute settings, where we sell a more focused product portfolio. Our Prime Vendor model allows us to provide cost savings to Prime Vendor customers, which, over time, supports incremental purchasing of our Medline Brand products and greater scale across our operations. As our scale grows, we are able to realize further efficiencies by offering superior or similar quality to third-party products at a more cost-effective price. We believe that Medline Brand conversion is mutually beneficial for both our customers and us-the value we provide customers at the outset of a Prime Vendor agreement meaningfully increases over time, as they accrue savings by purchasing our lower cost Medline Brand products, while our profitability grows given the enhanced margin profile of Medline Brand products. This compelling value proposition and supply chain relationship with our customers supports our greater than 98% average Prime Vendor retention rate over the past five years.

A portion of Supply Chain Solutions products sold to existing Prime Vendor customers has like-for-like Medline Brand product equivalents, representing a potential gross profit uplift consistent with our historical margin differentials if such products were converted for Medline Brand products. While we historically have earned higher margins upon conversion from third-party national brand products to like-for-like Medline Brand products, because of the lower average prices for Medline Brand products, there is typically a negative impact on net sales upon the conversion of Supply Chain Solutions products to like-for-like Medline Brand products if volume is assumed to be constant. For additional information on potential risks relating to this conversion opportunity, please see Part I, "Item 1A—Risk Factors—Risks Related to Our Business, Industry and Operations—Our failure to establish and maintain Prime Vendor relationships may cause our revenue to decline."

Our Distribution Network

We have a differentiated distribution network of 70 global distribution centers, warehouses, cross-docks, and transship facilities, 45 of which are in the United States, strategically located to provide next-day delivery to 95% of our U.S. customer base. We utilize artificial intelligence ("AI") and robotics technology in over 26 million square feet of warehouse space in the United States to improve efficiency and capacity to optimize distribution logistics and maximize utilization. The products we distribute are packaged to meet each customer's individual needs and to be "put-away-ready," which streamlines the customer's unloading and shelving process. We also operate our own fleet of more than 2,100 MedTrans trucks that deliver our products across care settings within the United States. As of December 31, 2025, we had approximately 25% in incremental capacity across our platform to support our long-term growth.

Our Commercial Platform

Our deep connectivity to our customers is driven by the strength of our dedicated and tenured commercial team. We have a U.S. commercial team of approximately 4,000 people across all points of care, which includes account managers, product specialists, specialized clinical resources, customer service representatives, supply chain specialists, Prime Vendor analysts, and a robust leadership team dedicated to driving efficiencies for our customers through their teams. We have created an entrepreneurial environment that empowers our salesforce to work with our product managers to create innovative products that meet market demand. We have a team devoted to each channel in the United States and each region or country internationally, which allows our salesforce teams to develop market-specific knowledge.

Research and Development

We have a track record of successfully bringing new products to market, with more than 2,300 granted patents and more than 450 U.S. Food and Drug Administration ("FDA") 510(k) clearances. Over the last three years, we have successfully launched more than 250 new products.

Competition

Our value proposition is derived from our integrated business model, the breadth of our Medline Brand portfolio, our differentiated supply chain, and the overall quality and cost of our products. As a result of our integrated business model, our competitors include both other leading med-surg product manufacturers and distributors.

Similar to us, other leading med-surg product manufacturers produce a wide range of med-surg supplies. However, unlike us, many of these competitors are reliant upon third-party distributors to deliver their products to customers. By nature of being a distributor, Medline has direct access to and manages the end customer relationships. This enables us to offer a complete solution as a manufacturer and a distributor, offering our customers what we believe to be best-in-class supply chain logistics, and driving value through our brand.

Additionally, other distributors of med-surg products similarly connect the fragmented supplier and provider bases and aggregate inventory from suppliers to deliver products to customers, such as McKesson, Cardinal Health, Owens & Minor, and Henry Schein. These distribution companies compete with us for Prime Vendor agreements. However, we believe that many of these competitors do not benefit from the scale and scope of our vertical integration or commercial excellence, and thus are not able to provide the same magnitude of cost savings, value, and holistic solutions that we deliver for our customers.

Production and Raw Materials

We manufacture approximately one-third of our Medline Brand products, which are primarily Class I and II medical devices, through our 30 manufacturing facilities, of which 24 are in North America. We purchase many of the components and raw materials used in manufacturing our products from numerous suppliers. We focus our manufacturing capabilities on products where we can leverage technology and automation to drive higher quality and lower costs to better serve our customers. For the vast majority of the other two-thirds of our Medline Brand products, we work closely with our network of more than 600 global partners across approximately 40 countries, many of whom have decades-long exclusive relationships with us. The breadth of our global sourcing partnerships provides diversification and strengthens our resiliency, with no single sourcing partner accounting for more than 5% of total spend as of December 31, 2025.

We also have plans and measures in place to help ensure continuity of supply while maintaining high quality and reliability. Generally, we have been able to obtain adequate supplies of such raw materials and components. However, due to the FDA's manufacturing requirements and those of other regulatory authorities, we may not be able to quickly establish additional or replacement sources for certain components, materials or processes if we experience a sudden or unexpected reduction or interruption in supply or services and are unable to develop alternative sources.

Human Capital Resources

At Medline, our relentless focus on the customer drives our human capital strategy, which revolves around attracting, developing, and retaining employees to provide the best products and services for our customers. We have developed a strong foundation that drives our recruitment, retention and development efforts. We are committed to supporting the personal and professional development of our employees, as well as providing competitive benefits and a safe, inclusive workplace.

As of December 31, 2025, we employed over 45,000 employees worldwide, with over 26,000 located in the United States. Our largest non-U.S. employee populations are in Mexico, Dominican Republic, India, Canada, Slovakia, France, China, Japan, Germany, and Australia. None of our employees in the United States are unionized, though some of our employees in Mexico belong to unions. In Germany and the Netherlands, employees are represented through Works Councils; in France and Spain, employees are represented through both Works Councils and industry-wide collective bargaining agreements; and in Belgium and Italy, employees are also represented through industry-wide collective bargaining agreements. In Australia, certain employees are represented by an enterprise bargaining agreement; in Japan, employees are represented through a Work Council; and in Vietnam, employees are represented through a collective bargaining agreement. We believe that our positive employee relations and total employee experience drive the continual growth of our workforce.

Culture and Values

Our culture is grounded in a customer-focused, collaborative, and performance-driven approach, guided by core values emphasizing relentless customer focus, agility and flexibility, problem-solving, drive to succeed, purposeful candor, and the importance of relationships. Employees are encouraged to exercise judgment, work transparently with customers, and contribute meaningfully to our mission to make healthcare run better.

Talent Attraction and Development

We seek to attract employees whose skills, experience, and motivation align with our operational and technical needs. Through continual improvement of internal processes, an awareness of market and candidate driven trends, and in partnership with vendors and other outside organizations, our talent acquisition programs focus on efficient hiring processes, market awareness, and building a diverse pipeline of candidates. We support development through consistent performance management processes and early career opportunities to take on additional responsibilities to demonstrate their competencies and drive to succeed and on-the-job responsibility augmented by formal training and development to refine technical and leadership skills. New sales representatives participate in comprehensive training programs, and product managers have targeted development pathways through all stages of their careers, from mandatory onboarding offerings to advanced classes that provide the necessary skills with increasing levels of responsibility, to support progression over time.

Employee Engagement and Inclusion

We believe our employees' ability to communicate and cooperate effectively across functional and departmental teams positively impacts our performance. We engage in various listening strategies and foster engagement through survey feedback mechanisms, anonymous employee feedback platform, focus groups, increased attention to onboarding and offboarding feedback, pulse surveys on remote work needs, and other listening strategies. Insights from these efforts inform workplace improvements. We also support an inclusive environment through Employee Resource Groups and leadership training initiatives designed to reduce bias in talent decisions and strengthen representation across the company.

Health, Safety, and Well-Being

We are committed to maintaining a safe workplace and supporting the physical, emotional, and financial well-being of our employees. We provide competitive health and benefits programs, access to assistance resources where available, and opportunities for community involvement through charitable giving, including financial giving and in-kind giving such as product donations.

Intellectual Property

We rely upon patents, trademarks, copyrights, trade secrets and other intellectual property rights to maintain and improve our competitive position. We have a large portfolio of intellectual property, including more than 2,300 granted patents as well as trademark registrations protecting our notable brands, including Medline, Curad, Microtek, Hudson, and Proxima.

We consider the trademarks and know-how that we own to be material to our business. However, other than the Medline mark, we do not consider our business to be materially dependent upon any individual trademark registration or trade secret. In the aggregate, we consider our more than 2,300 granted patents to be material to our business. However, no single patent or group of related patents is material to our business as a whole or any segment of our business.

We believe that we have taken all necessary steps to protect our intellectual property rights, but no assurance can be given that we will be able to successfully enforce or protect our rights in the event that they are infringed upon or challenged by a third party. See Part I, "Item 1A —Risk Factors—Risks Related to Regulation and Legal Proceedings—Any failure to obtain, maintain, protect and enforce our intellectual property rights, or the failure of the strength or scope of our intellectual property rights, could harm our business, financial condition, and results of operations" and "—Risks Related to Regulation and Legal Proceedings—We may become subject to litigation brought by third parties claiming infringement, misappropriation, or other violation by us of their intellectual property rights."

Government Regulation

Our operations and products are subject to extensive regulation by numerous governmental regulatory authorities, including U.S. and other international regulatory authorities, and other government agencies inside and outside the United States. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, design, materials, testing, safety, efficacy, quality, purity, manufacturing, methods, controls, testing, screening, recordkeeping, reporting, processing, storage, registration, authorization, licensing, permitting, labeling, advertising, marketing, distribution, offer for sale, sale, use, expiration, pricing, reimbursement, import, export, clinical trials, post-marketing surveillance of our products, the registration of our facilities, and the claims that we make about our products. The United States and other countries where we sell healthcare and other regulated products, including drugs, human cell and tissue products, dietary supplements, cosmetics, certain foods, and consumer products subject such products to their own clearance, authorization, approval, registration, listing, labeling, manufacturing, recordkeeping, reporting, and other regulatory requirements regarding the performance, safety, and quality of such products. We are also subject to healthcare and other regulations and enforcement by the federal government and the states and foreign governments and authorities in the locations in which we conduct our business. The U.S. governmental and regulatory authorities that enforce such laws and rules, and that issue guidance on compliance with such laws and rules include, without limitation, the FDA, the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the U.S. Department of Health and Human Services ("HHS"), the HHS Office of Inspector General, U.S. Environmental Protection Agency ("EPA"), the Federal Trade Commission ("the FTC"), Consumer Product Safety Commission ("CPSC"), the U.S. Department of Justice ("DOJ") and individual U.S. Attorney offices within the DOJ, as well as state and local governments. Our business is also affected by patient and data privacy and security laws, government payer cost containment initiatives, government reimbursement laws and regulations, environmental, health, and safety laws and regulations, as well as laws and regulations with respect to the sale, transportation, storage, handling, and disposal of hazardous or potentially hazardous substances, and safe working conditions. Our business also maintains contracts with governmental agencies and such contracts are subject to various government procurement laws and regulations, required contract provisions, and other requirements relating to contract formation, administration and performance. Failure to comply with applicable laws and regulations or with contractual or other requirements may result in monetary damages and criminal or civil penalties as well as termination of our government contracts or our suspension or debarment from government contract work.

The regulations to which we are subject are complex and have tended to become more stringent over time. If our business expands in certain ways, including through the offering of new products and services or entering into new geographic areas, we may be subject to new and additional regulatory requirements. The foreign, federal, state, and local regulatory authorities have broad inspection and enforcement powers, including the ability to suspend or limit the distribution of products, suspend, revoke, or terminate our product and facility licenses, permits, and authorizations, request the cessation of distribution and shipments of certain products due to regulatory, safety, or other issues, seize or order the recall of our products, issue safety, quality, or other communications to the public or healthcare providers, enforce laws related to marketing, including promotion of off-label uses of products, and impose injunctions and significant criminal, civil, and administrative sanctions for violations of laws and regulations. Any adverse regulatory or other action, including any adverse press releases or other communications from regulators, may impact our business practices and operations, including by limiting our ability to effectively market, ship, and sell our products, affecting the production and distribution of products by our manufacturing facilities, subjecting us to significant liability, and limiting our ability to obtain future authorizations. Although we are subject to international government regulations in the international end markets where we operate and/or provide our products, these regulations do not have a material impact on our products as no international market represents more than 3% of our net sales.

Government Regulation of Medical Devices

Our medical devices are subject to regulation by numerous government agencies, including the FDA and comparable state and foreign agencies. Regulations of the FDA and other regulatory agencies in and outside the United States impose extensive compliance and monitoring obligations on portions of our business. The FDA and other U.S. and foreign governmental agencies regulate, among other things, with respect to medical devices: design, development, and manufacturing; testing, registration, listing, labeling, content, and language of instructions for use and storage; clinical trials; product safety; marketing, sales, and distribution; licensing and permit requirements; premarket clearance, approval and authorization; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval studies; and product import and export. The regulations to which we are subject are complex and have tended to become more stringent over time. If our business expands in certain ways, we may be subject to new and additional regulatory requirements. The FDA and state regulatory authorities have broad inspection and enforcement powers, including the ability to suspend or limit the distribution of products by our distribution centers; seize or order the recall of products; terminate, suspend, or revoke licenses and permits; and impose significant criminal, civil, and administrative sanctions for violations of these laws and regulations. Foreign regulations subject us to similar foreign enforcement powers. In addition, the FDA and other governmental and regulatory authorities, both in and outside the United States (including the FTC, the HHS Office of the Inspector General, the DOJ, and various state Attorneys General), monitor the promotion and advertising of our products. Any adverse regulatory or other action, including any adverse press releases or other communications from regulators, depending on its magnitude, may limit our ability to effectively market, ship, and sell our products, limit our ability to obtain future premarket authorizations, or result in a substantial modification to our business practices and operations.

FDA Premarket Clearance and Approval Requirements

Each medical device we wish to distribute commercially in the United States requires marketing authorization from the FDA prior to distribution, unless the device is exempt from premarket notification requirements. The type of marketing authorization necessary is generally linked to the classification of the device. The FDA classifies medical devices into one of three classes-Class I, II, or III-based on the degree of risk associated with a device and the level of regulatory control deemed necessary to ensure its safety and effectiveness. Class I devices that pose the least risk are subject only to General Controls applicable to all devices, such as requirements for device labeling, premarket notification, and adherence to current good manufacturing practices for devices as set forth in the Quality System Regulation ("QSR"). Class II devices that pose a moderate risk are subject to General Controls and may also be subject to Special Controls, such as performance standards, product-specific guidance documents, special labeling requirements, patient registries, or post-market surveillance. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through General and Special Controls, including devices that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential unreasonable risk of illness or injury.

Most Class I devices and some Class II devices are exempted by regulation from the 510(k) clearance requirement and can be marketed without prior authorization from the FDA. Class I and II devices that are not exempted are eligible for marketing through the 510(k) clearance pathway. By contrast, devices placed in Class III generally require premarket approval ("PMA") or de novo clearance prior to commercial marketing. The PMA approval process is more stringent, time-consuming and expensive than the 510(k) clearance process; however, the 510(k) clearance process has also become increasingly stringent and expensive. None of our products are currently approved under a PMA, and we have no plans for any indication or system improvement or extension that we believe would require a PMA. If, in the future, we were to file a PMA, we may be subject to additional regulatory requirements.

510(k) Clearance Process

To obtain 510(k) clearance, we must submit a premarket notification to the FDA demonstrating the proposed device to be substantially equivalent to a predicate device. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and it has either the same technological characteristics, or it has different technological characteristics, but the information provided in the 510(k) submission demonstrates that the device does not raise new questions of safety or effectiveness. The standard review process for 510(k)s is between six to nine months, dependent upon the type of 510(k) filing submitted. Although many 510(k) premarket notifications are cleared without clinical data, in some cases, the FDA may require clinical data to support substantial equivalence. In reviewing a premarket notification, the FDA may request additional information, including clinical data, which may significantly prolong the review process and clearance is never assured. Clinical trials generally require the submission of an investigational device exemption ("IDE") to the FDA for a specified number of patients and study sites, unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements. Clinical trials are subject to numerous requirements and institutional review board approval, oversight, and monitoring. Even if a trial is conducted, the results of clinical testing may not adequately demonstrate the safety and effectiveness of the device or be sufficient to obtain FDA clearance or approval for marketing.

After a device receives 510(k) clearance, any subsequent modification of the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require submission and approval of a de novo 510(k) or a PMA application in cases where new indications are sought for which there is no predicate. Non-significant changes are handled via internal documentation by the Company. Each manufacturer must judge the significance of modifications based on FDA 510(k) regulatory requirements and guidance documents. The FDA may review any such decision and may disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA may require the manufacturer to cease marketing and distribution and/or recall the modified device until 510(k) clearance or PMA approval is obtained. In the future, we may make modifications to our products after they have received FDA clearance and, in appropriate circumstances, determine that new clearance is unnecessary. However, the FDA may disagree with our determination, and, if the FDA requires us to seek 510(k) clearance or submit new PMA applications for any modifications to a previously cleared product, we may be required to cease marketing or distributing or recall the modified device until we obtain the required clearance or approval. We may also market or acquire products that are marketed without a 510(k) clearance, appropriate labeling, or that otherwise are marketed in violation of FDA requirements, since medical devices can be marketed only for the indications for which they are cleared or approved. Under these circumstances, we may also be subject to warning letters, significant regulatory fines, or other penalties, and we may no longer be able to market particular products for which a 510(k) clearance is required.

Post-Marketing Requirements

Numerous FDA regulatory requirements apply to devices we manufacture and distribute, including: compliance with the QSR, which require manufacturers and their suppliers to follow the applicable design, testing, processes, control, documentation, labeling, and other quality assurance procedures during the manufacturing process; establishment registration, which requires establishments involved in the production and distribution of medical devices intended for commercial distribution in the United States to register with the FDA; medical device listing, which requires manufacturers to list the devices they have in commercial distribution with the FDA; labeling regulations, which prohibit "misbranded" devices from entering the market, as well as prohibit the promotion of products for unapproved or off-label uses and impose other restrictions on labeling; post-market surveillance, including medical device reporting requirements which requires manufacturers to report to the FDA if their device may have caused or contributed to a death or serious injury, or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act that may present a risk to health. The FDA and other governmental and regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

The FDA enforces these requirements by inspection and market surveillance. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA may also inspect foreign facilities that export products to the United States. Failure to comply with applicable regulatory requirements may result in enforcement action or other actions by the FDA, which may include one or more of the following sanctions: adverse press releases and safety communications; requests to stop shipments; untitled letters or warning letters; fines, injunctions, and civil penalties; mandatory recall or seizure of our products; customer notifications and repairs or replacements; administrative detention or banning of our products; consent decrees; operating restrictions, partial suspension or total shutdown of production; refusing our request for 510(k) clearances for new product versions or modifications to existing product versions; revocation of 510(k) clearances previously granted; refusal to grant export approval for our products; and criminal prosecution and penalties. If any of these events were to occur, they could have a material adverse effect on our business, financial condition, and results of operations.

International Regulation of Medical Devices

Sales of medical devices outside the United States are subject to foreign government regulations, which vary substantially from country to country. In order to market our products in other countries, we must comply with applicable regulatory requirements and authorizations and approvals and safety and quality regulations in each country in which the product is marketed. The time required to obtain authorization, approval, or certification by a foreign country may be longer or shorter than that required for FDA clearance, and the requirements may differ significantly.

EU Regulation of Medical Devices

In the European Union ("EU") until May 25, 2021, medical devices were regulated by the Council Directive 93/42/EEC, which has been repealed and replaced by the Medical Device Regulation ("EU MDR"). Unlike directives, regulations are directly applicable in all EU member states without the need for member states to implement into national law. The EU extended the EU MDR transitional periods for certain medical devices until December 31, 2027 or December 31, 2028, depending on a device's risk class and subject to certain conditions to ensure continued access to medical devices for patients and to allow medical devices already placed on the market in accordance with the current legal framework to remain on the market, provided that the requirements of the transitional provisions are fulfilled.

In the EU, there is currently no premarket government review of medical devices. However, all medical devices placed on the EU market must meet general safety and performance requirements, and compliance with the general safety and performance requirements is a prerequisite for European conformity marking without which medical devices cannot be marketed or sold in the EU. EU MDR requirements regarding the distribution, marketing, and sale, including quality systems and post-market surveillance, have to be observed by manufacturers, importers, and distributors as of the application date (i.e., since May 26, 2021), including registration of economic operators and of devices (once the relevant modules of Eudamed are functional), surveillance, and vigilance requirements. The aforementioned EU rules are generally applicable in the European Economic Area which consists of the 27 EU member states plus Norway, Liechtenstein, and Iceland.

The NDA Approval Process

For any new drug products regulated under the Federal Food, Drug, and Cosmetic Act such as our ReadyPrep CHG cloth, a sponsor must submit a New Drug Application ("NDA"), to the FDA for review and approval. The NDA review and approval process may take multiple years and involves steps including the following:

- completion of preclinical studies and analytical and stability testing in accordance with applicable regulations;
- submission to the FDA of an Investigational New Drug ("IND") application, which must become effective before clinical trials may begin and must be updated annually and amended when certain changes are made;
- approval by an institutional review board, or IRB, or independent ethics committee, or IEC, at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, good clinical practice, or GCP, requirements, including informed consent, financial disclosure by investigators, and other clinical trial-related regulations, to establish the safety and efficacy of the investigational product for each proposed indication and other condition of use;
- preparation and submission to the FDA of an NDA;

- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance;
- satisfactory completion of FDA inspection of select clinical trial sites involved in conducting pivotal studies that generated the data in support of the NDA;
- payment of user fees for FDA review of the NDA; and
- FDA review and approval of the NDA, including of the proposed prescribing information and, where applicable, consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States.

Any approvals that we may ultimately receive could be withdrawn if required post-marketing trials or analyses do not meet the FDA requirements, which could materially harm the commercial prospects for our products.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution, or post-marketing study requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delay in obtaining, or failure to obtain, regulatory approval for our candidate products, or obtaining approval but for significantly limited use, would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Trade Regulations

The movement of products, services, and investment across borders subjects us to extensive trade regulations. A variety of laws and regulations in the countries in which we transact business apply to the sale, shipment, and provision of goods, services, and technology across borders. These laws and regulations govern, among other things, our import, export, and other business activities. We are also subject to the risk that these laws and regulations could change in a way that would expose us to additional costs, penalties, or liabilities. Some governments also impose economic sanctions against certain countries, governments, persons, and entities, both for unlawful or malign conduct and to discourage or prevent entities from abiding by other countries' laws. In addition to our need to comply with such regulations in connection with our direct activities, we also sell and provide goods, technology, and services to agents, representatives, and distributors who may export such items to customers and end-users. If we, or the third parties through which we do business, are not in compliance with applicable import, export control, or economic sanctions laws and regulations, we may be subject to civil or criminal enforcement action and varying degrees of liability. Such actions may disrupt or delay sales of our products or services or result in restrictions on our distribution and sales of products or services that may materially impact our business.

Anti-Boycott Laws

Under U.S. laws and regulations, U.S. companies and their subsidiaries and affiliates are prohibited from participating or agreeing to participate in unsanctioned foreign boycotts in connection with certain business activities, including the sale, purchase, transfer, shipping, or financing of goods or services within the United States or between the United States and countries outside of the United States. If we, or certain third parties through which we sell or provide goods or services, violate U.S. anti-boycott laws and regulations, we may be subject to civil or criminal enforcement action and varying degrees of liability.

Medline Industries, LP- Discipline *Confidential*

Date of Resolution	Facility	Description
08/03/2005	1401 N. Universal Ave Kansas City, MO 64120	**Case:** 2003031660 **Agency:** Missouri Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement, 5 years' probation **Summary:** Medline Industries Inc. distribution center at 1401 N. Universal Ave, Kansas City, MO 64120 (MO# DD2003031660) cited for failure to renew on time and deficient temperature control procedures. All issues resolved via Settlement Agreement effective 08/03/2005. License placed on probation for 5 years. The state conducted multiple inspections of the facility throughout the probationary period and found Medline to comply with all requirements. The probationary period closed in August 2010. **Corrective Actions:** Medline hired additional staff to monitor and ensure on-time license renewal. A temperature control room was constructed at the facility to ensure products are stored at the appropriate temperature and humidity.
12/07/2006	9101 Riverside Pkwy Lithia Springs, GA 30122	**Case:** N/A **Agency:** Florida Department of Health **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Temporary Suspension Lifted **Summary:** Medline Industries Inc. distribution center at 9101 Riverside Pkwy Lithia Springs, GA 30122 Non-Resident FL Permit (FL # 23:1470) suspended for operating without a FL Certified Designated Representative. The CDR resigned unexpectedly. Upon receipt of the notice of intent to suspend, Medline stopped all shipments into the state of FL. Permit was reinstated upon hiring of a new licensed Florida CDR. **Corrective Actions:** Qualified FL Certified Designated Representative hired for facility. Medline implemented a policy requiring all FL licensed distribution centers to maintain a backup Florida Certified Designated Representative on staff.
02/08/2008	2708 NE Waldo Rd. Gainesville, FL 32609	**Case:** 2007-37412 **Agency:** Florida Department of Health **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement **Summary:** Medline Industries, Inc. distribution center at 2708 NE Waldo Rd., Gainesville, FL 32609 FL Permit (FL # 22:1022) suspended for violations identified during a Florida BOP facility inspection. Medline, through Counsel, addressed the issues raised in the inspection and established that the suspension was unjustified. The suspension was lifted 3 days later on January 22, 2008. Medline Industries, Inc. entered into a settlement agreement on 02/08/2008 with the FL Department of Health to resolve all issues related to the case. **Corrective Actions:** Medline conducted a thorough review of its policies and procedures and implemented an internal auditing program to ensure that all distribution centers comply with internal policies and procedures and state and federal regulations.
05/01/2008	149 New Camellia Blvd. Covington, LA 70433	**Case:** 2008006 **Agency:** Louisiana Board of Wholesale Drug Distributors **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Consent Decree **Summary:** Medline Industries Inc. distribution center at 149 New Camellia Blvd. Covington, LA 70433 (LA #4318) cited for failure to properly maintain copies of current customer licenses on-site. Licenses were maintained by Medline's Regulatory team at corporate headquarters. Medline entered a consent decree effective 05/01/2008 to resolve the alleged violation. **Corrective Actions:** Medline implemented digital storage of customer licenses to allow for on-demand access by distribution centers.

Medline Industries, LP- Discipline *Confidential*

07/08/2008	94-1420 Moaniani St. Waipahu, HI 96797	**Case #:** PHA 2008-71-L **Agency:** Hawaii Department of Commerce and Consumer Affairs **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, Inc. distribution center at 94-1420 Moaniani St., Waipahu, HI 96797 (HI # PWD 115) entered a settlement agreement and placed on probation for 5 years for failure to report disciplinary actions within 30 days. Medline submitted all required notices but missed the 30-day deadline. The probationary period ended in August 2013. **Corrective Actions:** Medline implemented a policy and procedure to notify licensing boards of disciplinary actions within the required reporting timelines.
09/06/2008	10601 Southport Dr. Orlando, FL 32824 _____ 401 Commerce Blvd. Oldsmar, FL 34677 _____ 4750 118th Ave N Clearwater, FL 33762	**Case #:** 2007-11783; 2007-36555; 2007-38894; 2007-38895; 2007-38896; 2007-39073; 2008-02011; 2008-11215 **Agency:** Florida Department of Health **Entity:** Medline Industries, Inc.; Medline Manufacturing & Services, LLC **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries Inc. and Medline Manufacturing & Services, LLC was cited for several violations related to distribution centers in Florida, including, failure to pass and maintain a Florida compliant pedigree, maintaining the wrong permit type for the activities performed (Florida required a repackager permit in addition to the existing manufacturer permit), distribution of saline to an unauthorized recipient, and storage of a prescription drug in an unlicensed raw materials storage facility. Medline challenged several violations, resulting in most being substantially reduced or removed. All issues were addressed and resolved to the satisfaction of the FL DOH. A settlement agreement was reached to resolve all matters and approved on 09/06/2008. **Corrective Actions** Medline instituted a Florida specific pedigree system to address the pedigree issues. The updated pedigree ensures that all applicable shipments to Florida have the required Florida documentation and comply with FL pedigree requirements (Note - these requirements have since been preempted by the federal Drug Supply Chain Security Act). Medline secured the repackaging permit to address the missing permit type. Medline instituted a new procedure for obtaining and maintaining customer licenses for all prescription drug purchases- this procedure generates an automatic block for any prescription drug order by an unlicensed customer. The prescription drug item unintentionally stored in the raw materials facility was properly disposed of and waste disposal procedures updated to prevent this from occurring in the future.
02/04/2009	5450 W. Stewart Ave. Wausau, WI 54401	**Case:** 08 PHM 037 **Agency:** Wisconsin Department of Regulation and Licensing **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Stipulation Order **Summary:** Medline Industries Inc. distribution center at 5450 W. Stewart Ave., Wausau, WI 54401 (WI # 1116-045) cited for missing policies and procedures and storage of drugs in a non-secure location following an inspection by the Wisconsin Department of Regulation & Licensing. Medline managed a portion of a Wisconsin hospital's warehouse. The inspector cited Medline for failure to install a dividing fence between the Medline warehouse and the hospital portion of the facility. All hospital products were owned by the hospital. Medline was also cited for failure to access policies and procedures during the inspection. Corrections were made and the facility re-inspected, to the satisfaction of the state. Medline entered a stipulation order effective 02/04/2009 to resolve the matter. **Corrective Actions:** Medline installed a locked fence to separate the hospital's owned products. Medline also completed a review of all facilities to ensure proper separation of products. On-site staff provided additional training on how to access current policies and procedures during an inspection.

Medline Industries, LP- Discipline *Confidential*

05/19/2009	94-1420 Moaniani St. Waipahu, HI 96797	**Case:** PHA 2009-7-L **Agency:** Hawaii Department of Commerce and Consumer Affairs **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, Inc. agreed to enter a Consent Order for discipline incurred in another jurisdiction (Wisconsin Case #: 08 PHM 037). **Corrective Actions:** See Corrective Actions for Case #: 08 PHM 037.
03/19/2010	1401 N. Universal Ave. Kansas City, MO 64120	**Case:** 2010-002994 **Agency:** Colorado State Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Stipulation **Summary:** Medline Industries, Inc. distribution center at 1401 N. Universal Ave, Kansas City, MO 64120 applied for a Colorado Out-of-State Wholesaler license. The CO Board of Pharmacy issued a conditional license until the facility's MO probation period ended. (See Case 2003031660 above). Medline informed the CO Board when the MO probationary period was completed. Upon completion of probation, the Board issued a full license. **Corrective Actions:** Medline successfully completed terms of probation in MO and CO.
07/18/2014	3301 Route 6 Middletown, NY 10940	**Case:** 27278 **Agency:** NY State Education Department- Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Consent Order **Summary:** Medline Industries, Inc. agreed to enter a Consent Order for discipline incurred in another jurisdiction (FL No. 2007-37412, LA No. 2008006, and WI No. 08 PHM 037). **Corrective Actions:** See corrective actions for FL No. 2007-37412, LA No. 2008006, and WI No. 08 PHM 037.
01/06/2021	1501 Harris Rd Libertyville, IL 60048	**Case:** A-2020-0054 **Agency:** Ohio Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, Inc. distribution center at 1501 Harris Rd Libertyville, IL 60048 (OH License #01-1985050) entered into a settlement agreement with the Ohio Board of Pharmacy for the sale of dangerous drugs to an unlicensed entity. Medline maintained a current and valid DEA license on file rather than the correct Terminal Distributor Dangerous Drugs license (TDDD). The facility's TDDD license expired at the time of the sale. Case resolved via Settlement Agreement effective 01/06/2021. **Corrective Actions:** Medline updated its customer license requirements for Ohio customers. Medline completed a review of all Ohio customers to verify the correct license type was on file and implemented increased verification checks of Ohio licenses.

Medline Industries, LP- Discipline *Confidential*

06/28/2021	1501 Harris Rd Libertyville, IL 60048	**Case:** 21-L-0048 **Agency:** Alabama Board of Pharmacy **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Order **Summary:** Medline Industries, Inc. distribution center at 1501 Harris Rd Libertyville, IL 60048 (AL Non-Resident Permit #193718) was fined for discipline incurred in another jurisdiction (OH A-2020-0054) **Corrective Actions:** See corrective action for OH A-2020-0054.
11/01/2022	1040 Enterprise Parkway South West Jefferson, OH 43162	**Case:** A-2022-0333 **Agency:** Ohio Board of Pharmacy **Entity:** Medline Industries, LP **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, LP distribution center at 1040 Enterprise Parkway South, West Jefferson, OH 43162 (OH License #01-30000190) entered a settlement agreement with the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file instead of the correct Terminal Distributor Dangerous Drugs license (TDDD). The TDDD license was added in May 2022. During the period of July 2021 to March 2022, the customer's TDDD license lapsed, and Medline shipped the customer product under the valid practitioner license. Case resolved via Settlement Agreement effective 11/01/2022. **Corrective Actions:** Medline updated customer licensing requirements for Ohio customers following OH Case # A-2020-0054. The shipments in this matter occurred while Medline was in the process of reviewing and updating all Ohio customer licenses. Medline licensing staff were also provided with additional training on Ohio license requirements.
12/19/2022	9670 NW 112th Ave Miami, FL 33178	**Case:** 2022-031132 **Agency:** FL Dept. Business and Professional Regulation, Div. of Drugs, Devices, and Cosmetics **Entity:** Medline Industries, LP **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, LP distribution center at 9670 NW 112th Ave, Miami, FL 33178 (FL WDD# #2220297) entered a settlement agreement for alleged violations of selling prescription drugs to an unauthorized recipient and failure to maintain proper records. Medline accepted a physician license for a customer which should have maintained a Healthcare Clinic Establishment Permit. The recordkeeping allegation related to missing NDC numbers on outbound packing slips and invoices. **Corrective Actions:** Medline updated customer licensing requirements for Florida customers and completed an extensive review of all FL customer licenses to verify the correct license type was on file. Medline determined the missing NDC number on the packing slip and invoice occurred due to an internal system error. The error was limited to DSCSA exempt products, i.e. IV fluids. A fix was implemented to correct the issue.

Medline Industries, LP- Discipline *Confidential*

07/19/2023 07/25/2023	1040 Enterprise Parkway South West Jefferson, OH 43162 251 Hilton Drive Jeffersonville, IN 47130	**Case:** A-2022-0307; A-2022-0184 **Agency:** Ohio Board of Pharmacy **Entity:** Medline Industries, LP **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, LP distribution centers at 1040 Enterprise Parkway South, West Jefferson, OH 43162 (OH License #01-30000190) and 251 Hilton Drive. Jeffersonville, IN 47130 (OH License #01-30000158) entered settlement agreements with the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. The sales occurred between July 2021 and January 2022. Medline maintained valid practitioner licenses on file for each customer instead of the correct d sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file instead of the correct Terminal Distributor Dangerous Drugs license (TDDD). Cases resolved via Settlement Agreement effective 07/19/2023 and 07/25/2023. **Corrective Actions:** Medline updated customer licensing requirements for Ohio customers following OH Case # A-2020-0054. The shipments in this matter occurred between July 2021 and January 2022 while Medline was in the process of reviewing and updating all Ohio customer licenses.
12/21/2023	2341 Lauwiliwili St. Kapolei, HI 96707	**Case:** PHA 2023-9-L **Agency:** Hawaii Department of Commerce and Consumer Affairs **Entity:** Medline Industries, Inc. **Type:** Administrative **Disposition:** Settlement Agreement **Summary:** Medline Industries, LP distribution center at 2341 Lauwiliwili St, Kapolei, HI 96707 (HI #) entered a Settlement Agreement for discipline incurred in another jurisdiction (OH A-2022-0333, OH A-2022-0307, OH A-2022-0184, and FL 2022-031132) **Corrective Actions:** See corrective actions for OH A-2022-0333, OH A-2022-0307, OH A-2022-0184, and FL 2022-031132.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	08/03/2005	MO	Kansas City	Jackson

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2003031660	Missouri Board of Pharmacy

Reason/Charge
Failure to Renew on Time; Temperature Control Deficiency

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
MO Board of Pharmacy/ Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries Inc. distribution center at 1401 N. Universal Ave, Kansas City, MO 64120 (MO# DD2003031660) cited for failure to renew on time and deficient temperature control procedures. All issues resolved via Settlement Agreement effective 08/03/2005. License placed on probation for 5 years. The state conducted multiple inspections of the facility throughout the probationary period and found Medline to comply with all requirements. The probationary period closed in August 2010.

Corrective Actions:
Medline hired additional staff to monitor and ensure on-time license renewal. A temperature control room was constructed at the facility to ensure products are stored at the appropriate temperature and humidity.

Original Signature (electronic, copies or stamps not accepted)

09/02/2024
Date

FLORIDA DEPARTMENT OF HEALTH

Jeb Bush
Governor

M. Rony François, M.D., M.S.P.H., Ph.D.
Secretary

CERTIFIED MAIL/RETURN RECEIPT REQUESTED

December 7, 2006

Andrew Stolarski
Vice President of Operations
Medline Industries, Inc.
9101 Riverside Parkway
Lithia Springs, GA 30122

RE: Prescription Drug Wholesaler Permit No. 23:01470

Dear Mr. Stolarski:

This letter serves as notification that the department intends to suspend permit no. 23:01470 issued to Medline Industries, Inc. as an Out of State Prescription Drug Wholesaler based upon the following facts, grounds and considerations:

Section 499.067(1)(a), Florida Statutes (F.S.), authorizes the department to deny, suspend, or revoke a permit if it finds that there has been substantial failure to comply with § 499.001-499.081, F.S., or Chapter 465, Chapter 501, or Chapter 893, the rules adopted under any of those sections or chapters, any final order of the department, or applicable federal laws or regulations or other state laws or rules governing drugs, devices, or cosmetics. The department may also suspend a permit if the applicant has not met the requirements for the permit.

Pursuant to s. 499.012(11)(a), F.S., each establishment that is issued an initial or renewal permit as a prescription drug wholesaler or an out-of-state prescription drug wholesaler must designate in writing to the department at least one natural person to serve as the designated representative of the wholesaler. Such person must have an active certification as a designated representative from the department and must also meet the requirements of Section 499.012 (11) (d) F.S.

Pursuant to s. 499.012(11)(f), F.S., a wholesale distributor may not operate under a prescription drug wholesaler permit or an out-of-state prescription drug wholesaler permit for more than 10 business days after the designated representative leaves the employ of the wholesale distributor, unless the wholesale distributor employs another designated representative and notifies the department within 10 business days of the identity of the new designated representative. Mr. David L. Magruder, the designated representative identified for permit no. 23:01470 has resigned his position. We have not received a "Notification of Designated Representative" form identifying a certified individual to replace him. As a result Medline Industries, Inc. does not have a designated representative as required by s. 499.012(11), F.S.

Pursuant to s. 499.012(11)(b)4., F.S., to be certified as a designated representative, a person must receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and ss. 499.001-499.081 and the rules adopted by the department governing the wholesale distribution of prescription drugs.

Accordingly, and pursuant to the above referenced facts and law, the department hereby intends to suspend permit no. 23:01470 issued to Medline Industries, Inc. as an Out of State Prescription Drug Wholesaler because you have not complied with s. 499.012(11)(f), F.S. and otherwise do not have a designated certified representative on file with the Department that meets the requirements of Section 499.012 (11) F.S. which is a substantial failure to comply with ss. 499.001 – 499.081, F.S. and is a failure to meet the requirements for the permit, for which the suspension is authorized pursuant to Sections 499.067 (1) (a); 499.067 (1) (b) 2. F.S.

Therefore, the department concludes that Medline Industries, Inc. no longer meets the requirements to continue to operate as an Out of State Prescription Drug Wholesaler in Florida and the permit will be suspended until you have designated in writing to the department a person with an active certification to serve as a designated representative who meets the requirements of Section 499.012 (11) F.S.

NOTICE OF RIGHTS TO HEARING AND APPEAL

You have the right to request an administrative hearing pursuant to sections 120.569 and 120.57, F.S., if you wish to challenge the intended agency action to suspend your permit. Such proceedings are governed by sections 120.569 and 120.57, F.S., and Rules 28-106 and 28-107, Florida Administrative Code. Request for a hearing, formal or informal, must comply with Rule 28-107.004, Florida Administrative Code.

You have the right to be represented by counsel or other qualified representative, at your expense; to present evidence and argument; to call and cross-examine witnesses; and to have subpoena and subpoena duces tecum issued on your behalf if a hearing is requested.

A petition for administrative hearing must be in writing and must be received by the Agency Clerk for the Department, within twenty-one (21) days from the receipt of this complaint. The address of the Agency Clerk is 4052 Bald Cypress Way, BIN # A02, Tallahassee FL 32399-1703. The Agency Clerk's facsimile number is 850-410-1448.

Mediation is not available as an alternative remedy.

Your failure to submit a petition for hearing within 21 days from receipt of this complaint will constitute a waiver of your right to an administrative hearing, under Florida Administrative Code Rule 28-106.111 and this complaint shall become a "final order".

Should this correspondence become a final order, a party who is adversely affected by it is entitled to judicial review pursuant to s 120.68, F.S. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings may be commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by the filing fees required by law, with the Court of Appeal in the appropriate District Court. The notice must be filed within 30 days of rendition of the final order.

Sincerely,

Rebecca R. Poston, R.Ph.
Executive Director
Drugs, Devices, & Cosmetics Program

RP/rb

Attachment 2a.

MEDLINE

Medline Industries, Inc. One Medline Place Mundelein, Illinois 60060.4486 1.800.950.0128 Fax 1.847.949.2643

Corporate Quality Assurance/Regulatory Affairs

December 11, 2006

Ms. Rebecca R. Poston, R.Ph.
Executive Director
Drugs, Devices & Cosmetics Program
Florida Department of Health
4052 Bald Cypress Way
Tallahasee, FL 32399

RE: Prescription Drug Wholesaler Permit No. 23:01470

Dear Ms. Poston,

We have received the communication regarding the suspension of Prescription Drug Wholesaler Permit N. 23:01470. Pursuant to our communication with Rebecca Burnett on November 28, we have blocked applicable shipments from this location into Florida and they are being supplied by a properly permitted facility.

We are in the process of qualifying a replacement designated representative for this location. We hope to have this completed within the next 60 days.

Please note that Mr. Andy Stolarski is retiring and should no longer be listed as a contact for this location. Please direct any questions regarding this facility to
Ms. Lara Simmons
Corporate Director, Regulatory Affairs
One Medline Place
Mundelein, IL 60060
Phone: 847.837.2759
Fax: 847.837.2787
Email: LSimmons@Medline.com.

Sincerely,

Lara N. Simmons
Corporate Director, Regulatory Affairs

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	12/07/2006	GA	Lithia Springs	Douglas
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		Florida Department of Health		
Reason/Charge				
Medline's Florida Certified Designated Representative unexpectedly resigned.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Florida Department of Health/ Medline Industries, Inc.			Administrative Action	
Name of Business/Industry/Entity				
Medline Industries, Inc.				

Provide explanation below:

Medline Industries Inc. distribution center at 9101 Riverside Pkwy Lithia Springs, GA 30122 Non-Resident FL Permit (FL # 23:1470) suspended for operating without a FL Certified Designated Representative. The CDR resigned unexpectedly. Upon receipt of the notice of intent to suspend, Medline stopped all shipments into the state of FL. Permit was reinstated upon hiring of a new licensed Florida CDR.

Corrective Actions:
Qualified FL Certified Designated Representative hired for facility. Medline implemented a policy requiring all FL licensed distribution centers to maintain a backup Florida Certified Designated Representative on staff.

Original Signature (electronic, copies or stamps not accepted)

09/02/2026
Date

MEDLINE

Medline Industries, Inc. One Medline Place Mundelein, Illinois 60060.4486 1.800.950.0128 Fax 1.847.949.2643

Corporate Quality Assurance/Regulatory Affairs

December 11, 2006

Ms. Rebecca R. Poston, R.Ph.
Executive Director
Drugs, Devices & Cosmetics Program
Florida Department of Health
4052 Bald Cypress Way
Tallahasee, FL 32399

RE: Prescription Drug Wholesaler Permit No. 23:01470

Dear Ms. Poston,

We have received the communication regarding the suspension of Prescription Drug Wholesaler Permit N. 23:01470. Pursuant to our communication with Rebecca Burnett on November 28, we have blocked applicable shipments from this location into Florida and they are being supplied by a properly permitted facility.

We are in the process of qualifying a replacement designated representative for this location. We hope to have this completed within the next 60 days.

Please note that Mr. Andy Stolarski is retiring and should no longer be listed as a contact for this location. Please direct any questions regarding this facility to
Ms. Lara Simmons
Corporate Director, Regulatory Affairs
One Medline Place
Mundelein, IL 60060
Phone: 847.837.2759
Fax: 847.837.2787
Email: LSimmons@Medline.com.

Sincerely,

Lara N. Simmons
Corporate Director, Regulatory Affairs

Jeb Bush
Governor

FLORIDA DEPARTMENT OF HEALTH

M. Rony François, M.D., M.S.P.H., Ph.D.
Secretary

CERTIFIED MAIL/RETURN RECEIPT REQUESTED

December 7, 2006

Andrew Stolarski
Vice President of Operations
Medline Industries, Inc.
9101 Riverside Parkway
Lithia Springs, GA 30122

RE: Prescription Drug Wholesaler Permit No. 23:01470

Dear Mr. Stolarski:

This letter serves as notification that the department intends to suspend permit no. 23:01470 issued to Medline Industries, Inc. as an Out of State Prescription Drug Wholesaler based upon the following facts, grounds and considerations:

Section 499.067(1)(a), Florida Statutes (F.S.), authorizes the department to deny, suspend, or revoke a permit if it finds that there has been substantial failure to comply with § 499.001-499.081, F.S., or Chapter 465, Chapter 501, or Chapter 893, the rules adopted under any of those sections or chapters, any final order of the department, or applicable federal laws or regulations or other state laws or rules governing drugs, devices, or cosmetics. The department may also suspend a permit if the applicant has not met the requirements for the permit.

Pursuant to s. 499.012(11)(a), F.S., each establishment that is issued an initial or renewal permit as a prescription drug wholesaler or an out-of-state prescription drug wholesaler must designate in writing to the department at least one natural person to serve as the designated representative of the wholesaler. Such person must have an active certification as a designated representative from the department and must also meet the requirements of Section 499.012 (11) (d) F.S.

Pursuant to s. 499.012(11)(f), F.S., a wholesale distributor may not operate under a prescription drug wholesaler permit or an out-of-state prescription drug wholesaler permit for more than 10 business days after the designated representative leaves the employ of the wholesale distributor, unless the wholesale distributor employs another designated representative and notifies the department within 10 business days of the identity of the new designated representative. Mr. David L. Magruder, the designated representative identified for permit no. 23:01470 has resigned his position. We have not received a "Notification of Designated Representative" form identifying a certified individual to replace him. As a result Medline Industries, Inc. does not have a designated representative as required by s. 499.012(11), F.S.

Pursuant to s. 499.012(11)(b)4., F.S., to be certified as a designated representative, a person must receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and ss. 499.001-499.081 and the rules adopted by the department governing the wholesale distribution of prescription drugs.

Accordingly, and pursuant to the above referenced facts and law, the department hereby intends to suspend permit no. 23:01470 issued to Medline Industries, Inc. as an Out of State Prescription Drug Wholesaler because you have not complied with s. 499.012(11)(f), F.S. and otherwise do not have a designated certified representative on file with the Department that meets the requirements of Section 499.012 (11) F.S. which is a substantial failure to comply with ss. 499.001 – 499.081, F.S. and is a failure to meet the requirements for the permit, for which the suspension is authorized pursuant to Sections 499.067 (1) (a); 499.067 (1) (b) 2. F.S.

Therefore, the department concludes that Medline Industries, Inc. no longer meets the requirements to continue to operate as an Out of State Prescription Drug Wholesaler in Florida and the permit will be suspended until you have designated in writing to the department a person with an active certification to serve as a designated representative who meets the requirements of Section 499.012 (11) F.S.

NOTICE OF RIGHTS TO HEARING AND APPEAL

You have the right to request an administrative hearing pursuant to sections 120.569 and 120.57, F.S., if you wish to challenge the intended agency action to suspend your permit. Such proceedings are governed by sections 120.569 and 120.57, F.S., and Rules 28-106 and 28-107, Florida Administrative Code. Request for a hearing, formal or informal, must comply with Rule 28-107.004, Florida Administrative Code.

You have the right to be represented by counsel or other qualified representative, at your expense; to present evidence and argument; to call and cross-examine witnesses; and to have subpoena and subpoena duces tecum issued on your behalf if a hearing is requested.

A petition for administrative hearing must be in writing and must be received by the Agency Clerk for the Department, within twenty-one (21) days from the receipt of this complaint. The address of the Agency Clerk is 4052 Bald Cypress Way, BIN # A02, Tallahassee FL 32399-1703. The Agency Clerk's facsimile number is 850-410-1448.

Mediation is not available as an alternative remedy.

Your failure to submit a petition for hearing within 21 days from receipt of this complaint will constitute a waiver of your right to an administrative hearing, under Florida Administrative Code Rule 28-106.111 and this complaint shall become a "final order".

Should this correspondence become a final order, a party who is adversely affected by it is entitled to judicial review pursuant to s 120.68, F.S. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings may be commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Health and a second copy, accompanied by the filing fees required by law, with the Court of Appeal in the appropriate District Court. The notice must be filed within 30 days of rendition of the final order.

Sincerely,

Rebecca R. Poston, R.Ph.
Executive Director
Drugs, Devices, & Cosmetics Program

RP/rb

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

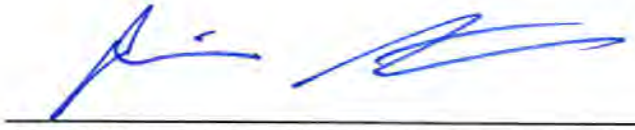
This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	02/08/2008	FL	Gainesville	Alachua
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2007-37412		Florida Department of Health		
Reason/Charge				
Inspection Deficiencies				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Florida Department of Health / Medline Industries, Inc.			Administrative Action	
Name of Business/Industry/Entity				
Medline Industries, Inc.				

Provide explanation below:

Medline Industries, Inc. distribution center at 2708 NE Waldo Rd., Gainesville, FL 32609 FL Permit (FL # 22:1022) suspended for violations identified during a Florida BOP facility inspection. Medline, through Counsel, addressed the issues raised in the inspection and established that the suspension was unjustified. The suspension was lifted 3 days later on January 22, 2008. Medline Industries, Inc. entered into a settlement agreement on 02/08/2008 with the FL Department of Health to resolve all issues related to the case.

Corrective Actions:
Medline conducted a thorough review of its policies and procedures and implemented an internal auditing program to ensure that all distribution centers comply with internal policies and procedures and state and federal regulations.



Original Signature (electronic, copies or stamps not accepted)

09/02/2026

Date

Final Order No. DOH-08-0203-S-MQA
FILED DATE - 2-8-08
Department of Health
By:
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

Case No.: 2007-37412

vs.

MEDLINE INDUSTRIES, INC.,

Respondent.
_____/

FINAL ORDER

In this matter, the Florida Department of Health is proceeding under the Florida Drug and Cosmetics Act, Chapter 499, Florida Statutes. The Parties request a final order adopting their settlement agreement.

Being fully advised, the Parties' request is granted. On or about February 8, 2008, the Parties fully executed their "Settlement Agreement for Final Order", which is incorporated by reference. The "Settlement Agreement for Final Order" is approved, and the parties are directed to comply with it.

DONE and **ORDERED** this 8TH day of February 2008, in Tallahassee, Leon County, Florida.

ANA M. VIAMONTE ROS, M.D., M.P.H.
STATE SURGEON GENERAL

By: FW
PAUL METTS, C.P.A., M.H.A.
DEPUTY SECRETARY

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been furnished via U.S. Mail, or fax delivery to: Edwin Bayo, Esq., Attorney for MEDLINE INDUSTRIES, INC., at Metzger, Grossman, Furlow & Bayo, L.L.C , 1408 North Piedmont Way, Tallahassee, Florida 32308, 850.385.4240 (facsimile) and via interoffice mail to Lynne A. Quimby-Pennock, Assistant General Counsel, Department of Health, 4052 Bald Cypress Way, Bin #C-65, Tallahassee, Florida 32399-3265 this 8 day of February 2008.

Deputy Agency Clerk
Department of Health
4052 Bald Cypress Way, Bin C-01
Tallahassee, Fl. 32399-3251

DELEGATION OF AUTHORITY
to
Deputy Secretaries and Chief of Staff

A. In accordance with the authority created in Sections 20.05(1)(a) and (b) and 20.43, Florida Statutes and vested in me as State Surgeon General for the Department of Health, the following authority is delegated:

1. Take all actions required for the effective direction and administration of the Department of Health in accordance with applicable Florida Statutes (F.S.), Florida Administrative Code (F.A.C.), and department policies.

2. In the absence of the State Surgeon General, each deputy is delegated authority to sign as the agency head or represent the State Surgeon General at any meetings within their respective areas, unless there is a specific delegation of authority.

3. In the absence of a deputy, the other deputies are delegated the authority to take all actions required for the effective administration and operation of that respective area, unless there is a specific delegation of authority.

4. Act as a hearing officer in proceedings required by Section 120.54(3)(c), F.S., (Hearings) and to enter any order in connection therewith.

5. Enter final orders in proceedings under Section 120.57, F.S. (Additional Procedures Applicable to Hearings).

6. Authorize policies and procedures within your respective areas; however, all department-wide policy and procedure changes that affect or have an impact on other areas such as statewide computer systems, standard audit practices, and workload for the Division of Administration, shall be coordinated with the appropriate division director. **The State Surgeon General approves and signs all department policies.**

7. Approve contracts (revenue and expenditure) and purchase orders $1 million or more. This authority may not be redelegated. **Exception: Fixed Capital Outlay contracts, change orders and additional FCO services authorizations are delegated to the Director of Administration, who may only redelegate to the Chief of General Services or Administrator of Design and Construction.**

8. Approve all grant applications and carryover requests greater than $250,000. Bureau of Revenue Management approval required for Central Office grant applications prior to submission to the awarding agency.

9. Approve the hiring of Senior Management Service and Selected Exempt Service employees at a bureau chief level or higher pursuant to Chapter 60L-33, F.A.C., and department policy.

10. Grant Career Service employees salary additives in excess of 10% in accordance with Rule 60L-32.0011, F.A.C., and department policy.

11. Grant employees an increase to base rate of pay in excess of 10%in accordance with Rule 60L-32.0011, F.A.C., and department policy.

12. Approve appointments of employees previously dismissed from the department or other state agency. Approve appointments of employees who resigned from the department or other state agency while under investigation; or pursuant to a settlement agreement; or in lieu of dismissal.

13. Approve exemptions under Section 435.07, F.S., for persons disqualified from employment under Section 435.04, F.S.

14. Issue decisions on collective bargaining grievances at Step 2, in accordance with the Florida Statutes, department policy, and the applicable collective bargaining agreement.

15. Authorize and approve out-of-state travel.

16. Approve Emergency Suspension Orders and Emergency Restriction Orders during the absence of the State Surgeon General.

17. Approve core contracts under Chapter 154, F.S., with the local Board of County Commissioners.

B. Exceptions to this authority, which require the approval of the State Surgeon General are

1. All changes to organization structure, functions, and programs involving the moving of positions or units between budget entities and divisions, or any action requiring the Department of Management Services and the Governor's Office of Policy and Budget approval.

2. Appointment or dismissal of county health department directors/administrators, children's medical services medical directors, division directors, or office directors.

C. This authority may be modified for specified periods of time as desired by the State Surgeon General.

D. These delegations may not be redelegated without the approval of the State Surgeon General.

8/6/07
Effective Date

Ana Maria Viamonte Ros
Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General
Department of Health

STATE OF FLORIDA
FLORIDA DEPARTMENT OF HEALTH
Medline Industries, Inc.
Case #2007-37412

SETTLEMENT AGREEMENT FOR FINAL ORDER

IT IS AGREED and STIPULATED by and between the State of Florida, Department of Health and MEDLINE INDUSTRIES, INC., that:

1. The Department of Health, through its Division of Medical Quality Assurance, Drugs, Devices and Cosmetics Program, (referred to as "the Department", 4052 Bald Cypress Way, Bin C-04, Tallahassee, Florida 32399 is responsible for, among other duties, under the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes (the Act) and the rules adopted there under, Rule 64F12 Florida Administrative Code, the regulation and permitting of prescription drug manufacturing and wholesaling within and into Florida.

2. The Department has investigated MEDLINE INDUSTRIES, INC., (referred to as "Medline") which holds a prescription drug wholesale permit, permit number 22:1022, located at 2708 NE Waldo Road, Gainesville, Floirda32609-3323.

3. The Department investigated Medline during the week of November 26, 2007, and found Medline to be operating in violation of Chapter 499, Florida Statutes (F.S.). The specific violations alleged include:

a. s. 499.005(1), & (4) F.S., and 499.069(1), F.S. in violation of s. 499.0121(1) F.S., and Rule 64F-12.014(4) Florida Administrative Code (F.A.C.) - holding or offering for sale any drug, device or cosmetic that is adulterated or

misbranded or has otherwise been rendered unfit for human or animal use. Establishment to be maintained in a clean and orderly manner to prevent the product from becoming contaminated with filth or injurious to health. (The surplus warehouse was unclean with spiders, spider webs, dead insect bodies, bird feces/droppings and feathers therein.)

b. ss. 499.005(1) & (4), F.S., in accordance to s. 499.006(9), F.S., holding for sale adulterated medical devices on its inventory shelves through a failure to quarantine outdated medical devices.

c. ss. 499.005(4), 499.0121, F.S. & Rules 64F-12.013, & 64F-12.015(7)(a) F.A.C., - Improper Prescription drug storage, lack of climate control.

d. s. 499.0121(3), F.S. – Failure to notify the Department of all prescription drug sources.

e. s. 499.005(14), F.S. – Receiving prescription drugs from an unauthorized source.

f. ss. 499.005(18), 499.0121(6), F.S., and Rules 64F-12.012(5), 64F12.001(2), and 64F-12.012(3)(a), F.A.C., – failure to have pedigrees readily available for inspection.

g. s. 499.0121(7), F.S., inadequate SOP (standard operating procedures) or P&P (policy and procedures), or failing to follow them.

h. s. 499.005(24), F.S., distribution of legend devices to the ultimate user without a prescription or order from practitioner.

i. s. 499.005(4), F.S., in violation of s. 499.0121(2), F.S.,- unrestricted access to prescription drugs in that prescription drugs, devices and/or cosmetics are left on a loading dock for pick-up/delivery, but the area does not have restricted access.

4. On or about November 27 and/or 28, 2007, seizure orders were placed on numerous items in Medline's surplus warehouse and one pallet of product within the climate-controlled warehouse.

5. On January 22, 2008, an Order of Emergency Restriction of Permit was issued by State Surgeon General, Ana M. Viamonte Ros, M.D., M.P.H., restricting the specific use of the facility.

6. A Final Order in this case will incorporate the following agreed upon terms and conditions:

a. All items under the seizure order that contain prescription drug products shall be destroyed at Medline's expense at a Florida Chapter 499, F.S., permitted facility; all other seized items shall be destroyed by Medline at Medline's expense. Within ten (10) days of the destruction, Medline shall submit documentation detailing the destruction of said items to the Compliance Officer of the Florida Drug, Device and Cosmetic Program, at 4042 Bald Cypress Way, MQA/HSE, Tallahassee, Florida 32399.

b. All products remaining at Medline's facility that were received from J & L Medical, Inc., located at 784 Old Checker Ct.,

Buffalo Grove, Illinois, between June 2007 through November 27, 2007, shall be destroyed at Medline's expense at a Florida Chapter 499, F.S., permitted facility, or if the products do not contain prescription drugs shall be destroyed by Medline at Medline's expense. Within ten (10) days of the destruction, Medline shall submit documentation detailing the destruction to the Compliance Officer of the Florida Drug, Device and Cosmetic Program, at 4042 Bald Cypress Way, MQA/HSE, Tallahassee, Florida 32399.

c. Medline shall pay a fine of FIFTY THOUSAND DOLLARS ($50,000.00) to the Florida Drug, Device and Cosmetic Trust Fund. Said payment shall be by certified check, cashier check or money, and shall accompany this executed Settlement Agreement. Said check shall be made payable to the Florida Drug, Device and Cosmetic Trust Fund.

d. The Order of Emergency Restriction, entered by the Department on January 22, 2008, shall be lifted upon the filing of the Final Order adopting and accepting the terms of this Settlement Agreement.

e. Medline shall undergo quarterly inspections by the Department at Medline's expense for one (1) year from the issuance of the Final Order, to ensure proper compliance with Chapter 499, Florida Statutes and the rules thereto. The Department shall provide an invoice for the inspection that shall be paid within thirty (30) days of receipt by Medline. Said payment shall be sent to the Compliance Officer of the

Florida Drug, Device and Cosmetic Program, at 4042 Bald Cypress Way, MQA/HSE, Tallahassee, Florida 32399. The Department retains the authority to enter the permitted facility/warehouse at any time to conduct inspections/investigations as authorized by Florida law.

f. Medline shall conduct a training program, within thirty (30) days of the execution of this Settlement Agreement For Final Order, for its facility employees educating the employees on the requirements of Chapter 499, Florida Statutes and the applicable rules. Within ten (10) days of the training, Medline shall submit documentation detailing the training to the Compliance Officer of the Florida Drug, Device and Cosmetic Program, at 4042 Bald Cypress Way, MQA/HSE, Tallahassee, Florida 32399.

g. Medline shall comply with all applicable Federal and state law and rules, including but not limited to Chapter 499 Florida Statutes, and its applicable rules. Medline shall comply with all pedigree and audit trail requirements for all prescription drugs purchased, held and /or distributed by Medline, including the authentication of any prescription drugs received. Medline shall ensure that any automated pedigree system employed, shall satisfy the requirements of Chapter 499, F.S. and the applicable rules thereto.

h. Medline shall maintain its facility in a clean, orderly and pest/bird free environment.

7. By execution of this Settlement Agreement For Final Order and by the filing of the subsequent Final Order in this cause, the Department and Medline intend to and do resolve all issues pertaining to the above referenced investigation.

8. Medline neither admits nor denies the violations allege in the inspection/investigation reports generated by the Department's investigators in this cause.

9. Upon entry of the Final Order adopting this Agreement, the Department will not seek further disciplinary action against Medline based on any of the alleged violations described in the above listed case number. However, if there are future violations of Chapter 499, F.S., or the rules adopted thereto, the above listed case will be considered aggravating circumstances and will be construed as previous violations for purposes of assessing the amount of the fine to be levied pursuant to section 499.066(3)(c), F.S.

10. Medline voluntarily enters into this Settlement Agreement for Final Order and waives the right to a hearing in this matter and all further proceedings to which it may be entitled by law or administrative rules. Medline hereby knowingly and voluntarily waives all right to challenge or to contest this Settlement Agreement or the Final Order issued by the Department in any forum now or in the future available to them, including the right to any administrative proceeding,

circuit or federal court action, or any appeal. Both parties agree not to appeal this Settlement Agreement or the Final Order to be issued in this matter.

11. The signatories hereto represent that they have read this Agreement and are authorized to execute it on behalf of their respective principals and as duly designated representatives, to fully bind such principals, as well as the Parties successors and assigns. The terms of this Agreement are effective on the date of the last signature below. The original will be filed with a Final Order with the Department Clerk. Each signer will receive a copy of this Agreement.

12. This document is a public record and contains information that is routinely published by the Department. Upon the filing of this Agreement and entry of a Final Order by the Department the existence of the above reference case number and all matters therein are no longer confidential and exempt from public disclosure. All documents or records created or submitted for compliance issues shall be a public record when filed with the Department.

13. Each party to this proceeding shall bear its own costs and attorney fees.

14. The absences of a prohibition specifically listed in this Agreement shall not be construed as permission to engage in any activity that otherwise is in violation of section 499.001-499.081, Florida Statutes, or the rules promulgated thereunder.

15. Upon the filing of this Settlement Agreement for Final Order, the parties, as well as any person who may claim by or through them, hereby waive,

release and discharge the other, and any of their employees, attorneys, agents or representatives from all claims arising out of any act or omission related to the investigation and settlement of this matter. This release applies to any and all claims of any kind, whether known or unknowns and whether direct, indirect or derivative.

16. Upon execution of this Agreement the State Surgeon General or her designee will issue a Final Order incorporating the terms hereof.

17. The parties agree that should any legal dispute arise concerning enforcing the terms of this Agreement, venue shall be in Leon County, Florida and this Agreement shall be interpreted in accordance with applicable Florida law.

WHEREFORE the Parties request a final order adopting this Agreement as final agency action.

For: Medline Industries, Inc.,

_____ February 7 2008
Lara N. Simmons
Corporate VP for QA and RA
Authorized Representative, Medline Industries, Inc.,

For the Department of Health - Drug, Device and Cosmetic Program
4052 Bald Cypress Way,
Tallahassee, Florida 32399, 850.245.4031 , 850.245.4682 Fax

_____ February 8 2008
Rebecca Poston, R.PH
Executive Director
Florida Drug, Device & Cosmetic Program
Department of Health

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	05/01/2008	LA	Covington	St. Tammany Parish

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2008006	Louisiana Board of Wholesale Drug Distributors

Reason/Charge
Customer Licenses

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
LA Board of WDD/ Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries Inc. distribution center at 149 New Camellia Blvd. Covington, LA 70433 (LA #4318) cited for failure to properly maintain copies of current customer licenses on-site. Licenses were maintained by Medline's Regulatory team at corporate headquarters. Medline entered a consent decree effective 05/01/2008 to resolve the alleged violation.

Corrective Actions:
Medline implemented digital storage of customer licenses to allow for on-demand access by distribution centers.

Original Signature (electronic, copies or stamps not accepted)

09/02/2026
Date

LOUISIANA BOARD OF
WHOLESALE DRUG DISTRIBUTORS

MEDLINE INDUSTRIES, INC. Covington, LA LICENSE NO. 4318	CONSENT ORDER ADMINISTRATIVE CASE NO. 2008006

In review of evidence presented to the Louisiana Board of Wholesale Drug Distributors (the "Board") addressing specific violation(s) of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors by MEDLINE INDUSTRIES, INC., Covington LA facility (the "Respondent", "Licensee"), acting herein by its authorized agent, to-wit: "Copies of current licenses for customers who are authorized by law or regulation to procure or possess drugs or devices shall be maintained for all customers that are shipped or sold drugs or devices. If customer licenses are maintained off site, a list of customer names, addresses, licenses numbers, and license expiration dates shall be maintained for all customers that are shipped or sold drugs or devices.", La. R.S. Title 37, Chapter 54, Section 3467, and LAC, Title 46, Part XCI, Section 311.D and "violating provisions of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors", La. R.S. Title 37, Chapter 54, Section 3474.1 and LAC Title 46, Part XCI, Section 101.

Upon consideration of the evidence presented to the Board, this Consent Order is voluntarily entered into by and between Respondent and the Board. Respondent acting through its authorized agent, hereby waives formal Notice of and its attendance at the Evidentiary Hearing for presentation of the Consent Order to the Board. However, as a condition precedent to submission of the proposed Consent Order to the Board, Respondent hereby acknowledges and understands that information may be presented to the Board with regards to the details of the case for the Board to understand the circumstances. It is further acknowledged and understood by Respondent that in the event the Board is not agreeable to enter into the proposed Consent Order and an Administrative Hearing is ultimately conducted, the Board which will be presiding over the case will possibly have heard information which may later be submitted at the scheduled hearing. If such hearing occurs, Respondent waives any right that it may have to recuse or remove any or all members of the Board for the purposes of an Administrative Hearing in the event the proposed Consent Order is not accepted by the Board, or if Respondent withdraws his consent to the proposed Consent Order prior to its final approval by the Board. Furthermore, Respondent has had the opportunity to, or has in fact consulted with, legal counsel with regards to the Consent Order and the waivers contained herein.

FINDINGS OF FACTS

1. Respondent possesses Louisiana License No. 4318 issued by the Board to wholesale distribute legend drugs and devices in the State of Louisiana. Such license was in effect on 3/5/2008 through the date of the evidentiary hearing in this matter.

2. Pursuant to LAC 46:XCI.311.D, a licensee is required to maintain copies of current licenses for customer who are authorized by law or regulation to procure or possess legend drugs or devices for all customers that are shipped or sold legend drugs or devices; if these license copies are maintained off site, a list of customers with customer names, addresses, license number, and license expiration dates shall be maintained on site for all customers shipped or sold legend drugs or devices.
3. On 3/5/2008, an inspection was conducted by the Board's representative which revealed that copies of customer licenses were not at the Covington LA facility. A verbal request to provide a customer listing which should be maintained at the Covington LA facility was made. The customer license list was not available.
4. Information was thereafter submitted by Respondent to the Board's inspector as per the inspector's request. In review of a customer listing ("Pedigree List") as provided by the Respondent, the inspector requested copies of customer licenses for 15 of the customers listed. Verbal explanation was given was that customer licenses are verified and the customer is entered electronically into the system as an authorized recipient but that no hard copy of the customer license is being maintained.
5. Respondent's conduct in failing to maintain customer license documents and/or a customer listing at the Covington LA site is in violation of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors, specifically LAC 46:XCI.311.D.
6. Disciplinary sanctions and/or fines are applicable against Respondent in accordance with the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors.

CONCLUSIONS OF LAW

1. It is unlawful for Respondent, as a licensee to wholesale distribute legend drugs and devices, to not maintain current customer license documents and/or a current customer listing on-site. LAC 46:XCI.311.D.
2. It is unlawful for Respondent, as a licensee to wholesale distribute legend drugs and devices, to violate any of the provisions of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors. La. R.S. 37:3474.1 and LAC 46:XCI.101
3. Respondent's violations of the provisions of the Louisiana Revised Statutes and Louisiana Administrative Codes for Wholesale Drug Distributors constitute lawful grounds for the Louisiana Board of Wholesale Drug Distributors, upon due notice of hearing and proof of such violations, to assess a fine, revoke, suspend, or otherwise discipline Respondent's license as provided by law. La. R.S. 37:3474.1 and LAC 46:XCI.701 et seq.

DECISION

4. Respondent is hereby assessed a fine in the amount of $2,000 for its failure to properly maintain copies of current licenses for customers shipped or sold legend drugs or devices and/or a customer listing on site. Said fine to be paid on the effective date of

this Consent Order. No practice restrictions are placed on Respondent's license issued by the Board.

5. The existence and terms of this Consent Order will not be confidential or privileged information in accordance with the laws regarding public records.
6. Respondent hereby releases the Board, its representative, and attorney from any obligations or liability in their endeavors to administer this Consent Order.
7. The effective date of this Consent Order shall be such date it is accepted by the Board.
8. Respondent, through its authorized agent, declares that, before signing this Consent Order, it has carefully read this document, and it knows and understands the contents thereof, it signs it as an act of it own free will, it understands its meaning and effect, it has been given the opportunity to consult with an attorney, it voluntarily waives all rights to formal notice and a formal public hearing, as well as its appearance at the proceedings, and it consents to this Consent Order.

THUS DONE AND PASSED, on the 1 date of May, 2008, at the City of Mandeville, Parish/County of Lake, Louisiana/Illinois, in the presence of the two undersigned competent witnesses, who hereunto sign their names with Appearer and me, Notary, after due reading of the whole

WITNESSES:

MEDLINE INDUSTRIES, INC.
Covington LA

Signature of Authorized Agent

Lara N Simmons
Print Name of Authorized Agent

Notary Public

OFFICIAL SEAL
SUSAN MILLER
Notary Public - State of Illinois
My Commission Expires Jul 16, 2011

LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS
12046 Justice Avenue, Suite C
Baton Rouge, LA 70816
(225) 295-8567 Fax (225) 295-8568 lsbwdd@bellsouth.net www.lsbwdd.org

April 28, 2008

Lara N. Simmons, VP-QA/RA
MEDLINE INDUSTRIES, INC.
One Medline Place
Mundelein, IL 60060

RE: Louisiana License No. 4318
Administrative Docket No. 2008006

CERTIFIED MAIL
No. 7007 3020 0000 4310 0031
Return Receipt Requested

Dear Lara Simmons:

As you may recall, the Board is mandated by law to license and regulate the wholesale distribution of legend drugs and devices in Louisiana in accordance with the Louisiana Revised Statutes and Louisiana Administrative Codes for wholesale drug distributors. This letter will acknowledge receipt of your response dated 4/3/2008. This letter is also intended to respond to any inquiries you may have regarding the deficiencies found during the inspection which occurred on 3/5/2008 at MEDLINE INDUSTRIES, INC.'s Covington LA distribution facility.

Pursuant to the Louisiana Revised Statutes and Louisiana Administrative Codes, specifically LAC 46:XCI.311.D, a licensee should maintain copies of current licenses which authorizes a customer to procure and possess legend drugs and devices. If these customer licenses are maintained off site, a list of customers including customer names, addresses, license number, and the license expiration dates shall be maintained for all customers that are shipped or sold drugs or devices.

On 3/5/2008, the Board's inspector discovered that copies of customer licenses which authorize the customer to procure and possess legend drugs/devices or a listing of customers' license information were not being maintained at the Covington LA facility.

A verbal request was made by the inspector of a customer list which should have been maintained at the Covington LA facility. After receiving and reviewing a copy of the customer list, as referred to by Medline as their "Pedigree List", the inspector requested copies of 30 customer licenses from the listing. Of the requested customer license copies, the inspector found that 70% of the licenses requested were either not acceptable licenses or were not available.

It is evident that MEDLINE INDUSTRIES, INC. was in violation of LAC 46:XCI.311.D at the time of the inspection on 3/5/2008. The Louisiana Revised Statutes and Louisiana Administrative Codes for wholesale drug distributors, more particularly LA RS 37:3474.1, provides that, after due notice and hearing, MEDLINE INDUSTRIES, INC.'s license may be sanctioned and/or it may be assessed a fine for its actions or omissions. Fines alone may include an assessment of $1,000 per violation

Bob Brondin, Chairman | William Crates, Vice-Chairman | Randall Brooks, Secretary/Treasurer | John Liggio, Executive Director/Inspector
Hershel Paul, Board Member | Andy Milligan, Board Member | Wayne Gremillion, Board Member | Eric Vidrine, Board Member | Kimberly B. Barpier, Executive Assistant

per day. It is the Board's objective to regulate the industry by correcting behavior. Such is accomplished by imposing sanctions for wrongful conduct.

It is hoped that the above detailed violation(s) as corrected will not occur in the future. Therefore, in an effort to amicably resolve the issues regarding the violation(s) which did occur, I, as the Board's appointed investigating/compliance officer, extend an offer to you which would impose a total fine of $2,000. This proposed sanction does not impose any restrictions on MEDLINE INDUSTRIES, INC.'s license.

If MEDLINE INDUSTRIES, INC. is agreeable to these terms, I have enclosed a Consent Order for your review and execution. Please have an authorized representative for your company sign the Consent Order in front of a Notary and two witnesses. Return the original, executed Consent Order along with a check made to the Louisiana Board of Wholesale Drug Distributors in the amount of the $2,000 fine to the Board's office within fifteen (15) days of receipt of this letter. You and/or a company representative will not be required to attend the evidentiary hearing at which the executed Consent Order will be presented to the full Board for acceptance, however you and/or another representative are welcome to attend.

In the event MEDLINE INDUSTRIES, INC. is not agreeable to this amicable resolution and wishes to contest the investigative findings in a hearing before the full Board, it has the right to do so. If such occurs, the current offer being proposed in this letter will no longer be viable.

We would like to bring this matter to disposition either by this amicable resolution or the pursuit of a formal hearing against MEDLINE INDUSTRIES, INC. before the Board at the next scheduled Board meeting. To do so, either way, we will need to prepare the necessary paperwork with all resolution documents. Again, please respond to this offer either by returning the executed Consent Order and fine payment or by written request for an administrative hearing. If your response is not received at the Board office within fifteen (15) days of receipt of this letter, the Board will begin steps towards the formal hearing with the issuance of subpoenas for witnesses and records.

We wish to keep an open line of communication with you. Please contact the Board office in the event you have any questions. Thank you for your cooperation in this matter.

Respectfully,

Wayne Gremillion
Board Member/Compliance Officer

/kbb
Encl: Consent Order
File
Cc: Gregg/ T Stoecker, Covington LA

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	07/08/2008	HI	Waipahu	Honolulu

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
PHA 2008-71-L	Hawaii Department of Commerce and Consumer Affairs

Reason/Charge
Late Discipline Reporting

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
HI DCCA / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. distribution center at 94-1420 Moaniani St., Waipahu, HI 96797 (HI # PWD 115) entered a settlement agreement and placed on probation for 5 years for failure to report disciplinary actions within 30 days. Medline submitted all required notices but missed the 30-day deadline. The probationary period ended in August 2013.

Corrective Actions:
Medline implemented a policy and procedure to notify licensing boards of disciplinary actions within the required reporting timelines.

Original Signature (electronic, copies or stamps not accepted)

09/02/2026
Date

LINDA LINGLE
GOVERNOR

JAMES R. AIONA, JR.
LT. GOVERNOR

LAWRENCE M. REIFURTH
DIRECTOR
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS

JO ANN M. UCHIDA
COMPLAINTS AND ENFORCEMENT OFFICER

STATE OF HAWAII
REGULATED INDUSTRIES COMPLAINTS OFFICE
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
LEIOPAPA A KAMEHAMEHA BUILDING
235 SOUTH BERETANIA STREET, NINTH FLOOR
HONOLULU, HAWAII 96813
FAX: (808) 586-2670
TELEPHONE: (808) 586-2660

HILO OFFICE
345 KEKUANAOA STREET, SUITE 12
HILO, HAWAII 96720

KONA OFFICE
KEAUHOU SHOPPING CENTER, ROOM 134A
78-6831 ALII DRIVE
KAILUA-KONA, HAWAII 96740

MAUI OFFICE
1063 LOWER MAIN STREET, SUITE C-216
WAILUKU, HAWAII 96793

KAUAI OFFICE
3060 EIWA STREET, ROOM 204
LIHUE, HAWAII 96766

July 8, 2008

Ms. Dianna J. Wolfe
Regulatory Affairs Specialist
Medline Industries, Inc.
One Medline Place
Mundelein, Illinois 60060

Re: RICO Case No. PHA 2008-71-L

Dear Ms. Wolfe:

I received the signed Settlement Agreement. One correction had to be made, and I apologize that we did not notice this earlier. On page 3, paragraph 5, the citation to HRS section 436B-19(13) was changed to HRS section 436B-19(15) which is the correct citation. Enclosed is a copy of the corrected replacement page. I will now forward the document to the executive officer of the Board of Pharmacy, and we will be notified as to whether it gets approved or not by the Board.

Very truly yours,

Bobbi Lum-Mew

Bobbi W.Y. Lum-Mew
Staff Attorney

/BLM
Enclosure

DARIA A. LOY-GOTO 6175
BOBBI W.Y. LUM-MEW 6299
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorney for Department of Commerce
and Consumer Affairs

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Wholesale Prescription Drug Distributor's License of	)	PHA 2008-17-L
MEDLINE INDUSTRIES INC.,	)	SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHBITS "1" THROUGH "5"
Respondent.	)	

241092407

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorneys, and Respondent MEDLINE INDUSTRIES INC. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS

1. At all relevant times herein, Respondent was licensed by the Board of Pharmacy (hereinafter the "Board") as a wholesale prescription drug distributor under License Number

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

PWD 115. The license was issued on or about October 3, 2005. The license will expire on or about December 31, 2009.

2. Respondent's mailing address for purposes of this action is One Medline Place, Mundelein, Illinois 60060.

3. RICO received information that disciplinary action had been taken against Respondent's licenses by the States of Missouri and Florida. Specifically, RICO received information regarding the following:

a). Respondent entered into a Settlement Agreement with the Missouri State Board of Pharmacy. Pursuant to the terms of a Joint Agreed Disciplinary Order, Respondent's Missouri drug distributor's license was placed on probation and Respondent was ordered to comply with certain terms and conditions. A true and correct copy of the Settlement Agreement and Joint Agreed Disciplinary Order dated July 19, 2005 in Settlement Agreement Between State Board of Pharmacy and Medline Industries, Inc., is attached as Exhibit "1";

b). Respondent was issued a Letter of Warning and Notice of Serious Violations by the Missouri State Board of Pharmacy. A true and correct copy of the Letter of Warning and Notice of Serious Violations dated February 15, 2007 regarding Medline Industries, Inc., is attached as Exhibit "2";

c). Respondent was issued an Order of Emergency Suspension of Permit by the State of Florida's Department of Health. Pursuant to the terms of the Order, Respondent's Florida prescription drug wholesaler's permit was immediately suspended . A true and correct copy of the Order of Emergency Suspension of Permit by the State of Florida's Department of Health dated January 14, 2008 in In Re: Emergency Suspension of the Permit of Medline Industries, Inc., is attached as Exhibit "3";

d). Respondent was issued an Order of Emergency Restriction of Permit by the State of Florida's Department of Health. Pursuant to the terms of the Order, Respondent's Florida prescription drug wholesaler's permit was immediately restricted. A true and correct copy of the Order of Emergency Restriction of Permit by the State of Florida's Department of Health dated January 22, 2008 in In Re: Emergency Restriction of the Permit of Medline Industries, Inc., is attached as Exhibit "4";

e). Respondent entered into a Settlement Agreement with the State of Florida's Department of Health. Pursuant to the terms of a Final Order, Respondent was, among other things, ordered to undergo quarterly inspections and pay a $50,000.00 fine. A true and correct copy of the Settlement Agreement for Final Order dated February 8, 2008 in Settlement Agreement for Final Order regarding Medline Industries, Inc., is attached as Exhibit "5."

4. RICO alleges that although Respondent reported the actions on a December 5, 2007 renewal application, Respondent failed to report the disciplinary actions within thirty (30) days as required by Hawaii law.

5. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(15) (failure to report disciplinary action within thirty days) and § 436B-19(17) (violating applicable laws or rules).

6. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein licensed as a wholesale prescription drug distributor by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the license and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's license.

6. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

7. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2008-17-L.

C. TERMS OF SETTLEMENT:

1. Probation. Respondent's wholesale prescription drug distributor's license is hereby placed on probation for a period of five (5) years. During the probationary period, Respondent agrees to comply with the following terms of the probation as set forth in paragraphs C.2, C.3, and C.4 below:

2. Comply with Terms of Missouri Probation. Respondent shall comply with the terms of its probation in the July 19, 2005 Settlement Agreement Between State Board of Pharmacy and Medline Industries, Inc.. During the probationary period, Respondent shall report to the Hawaii Board of Pharmacy, in writing, any additional action by the State of Missouri within ten (10) days of such action. During the probationary period, Respondent shall deliver to the Hawaii Board proof of Respondent's compliance with the Missouri Settlement Agreement.

3. Comply with Terms of Florida Final Order. Respondent shall comply with the terms of the February 8, 2008 Settlement Agreement for Final Order. During the probationary period, Respondent shall report to the Hawaii Board of Pharmacy, in writing, any additional action by the State of Florida within ten (10) days of such action. During the probationary period, Respondent shall deliver to the Hawaii Board proof of Respondent's compliance with the Florida Settlement Agreement.

4. Administrative fine. Respondent agrees to pay a fine in the amount of FIVE THOUSAND AND NO/100 DOLLARS ($5,000.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: Bobbi Lum-Mew, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this fully executed Settlement Agreement is returned to RICO.

5. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1, C.2, C.3 and C.4 above, Respondent's license shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the license to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new license until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become licensed again, Respondent must apply to the Board for a new license pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

6. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of wholesale prescription drug distributors in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

7. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.8, C.9, C.10 and C.11 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

8. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

9. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

10. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any

representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

11. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: _____, _____, _____.

MEDLINE INDUSTRIES INC.

By: _____
Its _____

DATED: Honolulu, Hawaii, JUL 0 8 2008

Bobbi W.Y. Lum-Mew
DARIA A. LOY-GOTO
BOBBI W.Y. LUM-MEW
Attorneys for Department of Commerce and Consumer Affairs

IN THE MATTER OF THE WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR'S LICENSE OF MEDLINE INDUSTRIES INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; PHA 2008-17-L; EXHBITS "1" THROUGH "5"

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

ELWIN D.H. GOO
Chairperson

DATE

MARK E. BROWN
Vice-Chairperson

LAURIE H. Y. KAWAMURA

KENT KIKUCHI

KARL H. MIYAMOTO

PATRICK ADAMS

STANLEY M. CHOW

PVL 09/05/07

STATE OF Illinois)
) SS.
COUNTY OF Lake)

On this 5 day of Jan, 200 8, before me personally appeared Lora Sones, to me known to be the person described, and who executed the foregoing instrument on behalf of Medline Industries as Corporate VP of C+P, and acknowledged that he/she executed the same as his/her free act and deed.

OFFICIAL SEAL
SUSAN MILLER
Notary Public - State of Illinois
My Commission Expires Jul 16, 2011

Name:
Notary Public, State of

My Commission expires: 7-16-2011

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	9/06/2008	FL	Multiple	Multiple
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
See Below		Florida Department of Health		
Reason/Charge				
Pedigree, Incorrect Permit, Distribution to Unauthorized Receipt, Storage				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
FL DOH / Medline Industries, Inc.			Administrative Action	
Name of Business/Industry/Entity				
Medline Industries, Inc.; Medline Manufacturing & Services, LLC				

Provide explanation below:

Medline Industries Inc. and Medline Manufacturing & Services, LLC was cited for several violations related to distribution centers in Florida, including, failure to pass and maintain a Florida compliant pedigree, maintaining the wrong permit type for the activities performed (Florida required a repackager permit in addition to the existing manufacturer permit), distribution of saline to an unauthorized recipient, and storage of a prescription drug in an unlicensed raw materials storage facility. Medline challenged several violations, resulting in most being substantially reduced or removed. All issues were addressed and resolved to the satisfaction of the FL DOH. A settlement agreement was reached to resolve all matters and approved on 09/06/2008.

Corrective Actions
Medline instituted a Florida specific pedigree system to address the pedigree issues. The updated pedigree ensures that all applicable shipments to Florida have the required Florida documentation and comply with FL pedigree requirements (Note - these requirements have since been preempted by the federal Drug Supply Chain Security Act). Medline secured the repackaging permit to address the missing permit type. Medline instituted a new procedure for obtaining and maintaining customer licenses for all prescription drug purchases- this procedure generates an automatic block for any prescription drug order by an unlicensed customer. The prescription drug item unintentionally stored in the raw materials facility was properly disposed of and waste disposal procedures updated to prevent this from occurring in the future.

Locations:
10601 Southport Dr., Orlando, FL 32824
401 Commerce Blvd, Oldsmar, FL 34677
4750 118th Ave N, Clearwater, FL 33762

Case #: 2007-11783; 2007-36555; 2007-38894; 2007-38895; 2007-38896; 2007-39073; 2008-02011; 2008-11215

Original Signature (electronic, copies or stamps not accepted)

09/02/2026
Date

Attachment 5.

Final Order No. DOH-08-2129-S-MQA
FILED DATE - 9-19-08
Department of Health
By: _____
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

Case No.: 2007-11783; 2007-36555;
2007-38894; 2007-38895;
2007-38896; 2007-39073;
2008-02011; 2008-11215

vs.

MEDLINE, INDUSTRIES, INC.,

Respondent.
_____/

FINAL ORDER

A Notice of Violation letter was sent to the Respondent by the Department on May 14, 2008. Having received an Offer of Settlement, which is attached hereto as Exhibit A, this matter is before the Department of Health for the entry of a final order.

The Offer of Settlement was executed on or about September 19, 2008 and submitted together with the payment.

The Offer of Settlement is accepted and incorporated by reference. The parties are directed to comply with the terms of the Agreement.

It is, therefore, ORDERED that this matter and proceeding be CLOSED.

DONE and **ORDERED** this 26 day of September 2008, in Tallahassee, Leon County, Florida.

ANA M. VIAMONTE ROS, M.D., M.P.H.
State Surgeon General

By: Rebecca R. Poston
Rebecca R. Poston, R.Ph.
Executive Director
Drugs, Devices and Cosmetics

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been furnished via U.S. mail to: **Edwin Bayo, Esq., Attorney for MEDLINE INDUSTRIES, INC., at Metzger, Grossman, Furlow & Bayo, L.L.C., 1408 North Piedmont Way, Tallahassee, Florida 32308**, this 24 day of September, 2008.

Deputy Clerk

cc: Lynne Quimby-Pennock, DOH 4052 Bald Cypress Way, Bin #C-65 Tallahassee, FL 32399
Richard Sands, DOH 4052 Bald Cypress Way, Bin #C-70

SETTLEMENT AGREEMENT

Medline Industries, Inc., Case No.: 2007-11783, Permit No.: 22:596; Case No.: 2007-36555, Permit No.: No valid permit since 12.21.2006; Case No. 2007-38894, Permit No. 20:168; Case No. 2007-38895, Permit No.: 21:166; Case No. 2007-38896, Permit No.: 07:545; Case No.: 2007-39073, Permit No.: None; Case No. 2008-02011, Permit No.: None; Case No. 2008-11215, Medline Manufacturing & Services, LLC Permit No.: None

Pursuant to Section 120.57(4), Florida Statutes (2007), the above named parties hereby enter into this global stipulation as disposition of the attached administrative action, in lieu of any other administrative proceedings authorized in Chapter 120, Florida Statutes. The terms herein become effective upon rendition of the final order which shall incorporate the Settlement Agreement.

STIPULATED FACTS

1) Medline Industries Inc., and Medline Manufacturing & Services, LLC, (hereinafter collectively known as "Medline") neither admit nor deny the alleged violations in the attached Notice of Violation.
2) During the time the alleged violations occurred, Medline held certain Florida permits including: Permit No.: 22:596, a prescription drug wholesaler; Permit No.:20:168, a prescription drug manufacturer; Permit No.: 21:166 an Over the Counter Manufacturer; and Permit No.: 07:545 a device manufacturer within the state of Florida; however Medline is alleged to have failed to have certain other permits in the Notice of Violation.
3) The Department is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 20.43, Florida Statutes (2007), and Chapter 499, Florida Statutes (2007).



CONCLUSIONS OF LAW

4) Medline, by and through its undersigned agent, admits that it is subject to the provisions of Chapter 499, Florida Statutes (2007), and the jurisdiction of the Department.

5) Medline admits that the findings set forth in the Notice of Violation, if proven, would constitute violations of Chapter 499, Florida Statutes (2007).

6) Medline agrees that the Department's acceptance of the Settlement Agreement constitutes disciplinary action within the meaning of Section 499.066, Florida Statutes (2007), and Rule 64F-12.024, Florida Administrative Code.

SETTLEMENT

7) Medline agrees to pay a fine of ONE HUNDRED FIFTY THOUSAND DOLLARS ($150,000.00), and acknowledges that payment, made payable to the Florida Drug, Device and Cosmetic Trust Fund, is enclosed with this agreement.

8.) Medline affirms the violations cited the Notice of Violation letter issued under these case numbers have been corrected or are being corrected immediately. Medline shall provide written documentation of the return of the seized products to a licensed reverse distributor within thirty (30) days of the execution of this agreement. The documentation shall be sent to the Florida Drug Device and Cosmetic Program Office, Department of Health, 4052 Bald Cypress Way, Bin C04, Tallahassee, FL 32399-3255. Upon receipt of documentation demonstrating the return of the seized products, the seizure order shall automatically be lifted.

9) Medline affirms that it shall comply with all provisions of the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes, and the rules adopted thereunder.

10) It is expressly understood that a violation of the terms of this Settlement Agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary actions may be taken.

11) Medline expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Settlement Agreement incorporated in the Final Order.

12) Medline waives the right to seek any attorney's fees or costs from the Department in connection with this disciplinary proceeding.

Corporate Seal:

By: _____ 9/19/08
President (or authorized agent) Date

Attested by: _____ _____
Corporate Secretary Date

By: Rebecca R Poston 9/26/08
Authorized DOH Representative Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	02/04/2009	WI	Wausau	Marathon

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
08 PHM 037	Wisconsin Department of Regulation and Licensing

Reason/Charge
Failure to Separate Products, Failure to retrieve Policies and Procedure during Inspection

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
WI DSPS/ Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries Inc. distribution center at 5450 W. Stewart Ave., Wausau, WI 54401 (WI # 1116-045) cited for missing policies and procedures and storage of drugs in a non-secure location following an inspection by the Wisconsin Department of Regulation & Licensing. Medline managed a portion of a Wisconsin hospital's warehouse. The inspector cited Medline for failure to install a dividing fence between the Medline warehouse and the hospital portion of the facility. All hospital products were owned by the hospital. Medline was also cited for failure to access policies and procedures during the inspection. Corrections were made and the facility re-inspected, to the satisfaction of the state. Medline entered a stipulation order effective 02/04/2009 to resolve the matter.

Corrective Actions:
Medline installed a locked fence to separate the hospital's owned products. Medline also completed a review of all facilities to ensure proper separation of products. On-site staff provided additional training on how to access current policies and procedures during an inspection.



Original Signature (electronic, copies or stamps not accepted)

09/02/2026

Date

Jim Doyle
Governor

Celia M. Jackson
Secretary

WISCONSIN DEPARTMENT OF REGULATION & LICENSING

1400 E Washington Ave
PO Box 8935
Madison WI 53708-8935
Email: web@drl.state.wi.us
Voice: 608-266-2112
FAX: 608-268-2264
TTY: 608-267-2416

November 18, 2008

Jan Hornick
Medline Industries Inc.
5450 W. Stewart Ave.
Wausau, WI 54401

Re: 08 PHM 037

Dear Ms. Hornick:

As you know, an inspector for the Department of Regulation and Licensing inspected Medline Industries on May 9, 2008. He found that several policies were missing, and the facility was storing prescription drugs in a non-secure location. It has been determined that these violations are grounds for discipline. I am the prosecuting attorney assigned to the case.

I have enclosed a proposed stipulation and order, which would resolve this matter without a hearing. If you are willing to resolve this case by agreement, please sign and return the stipulation and order by **December 9, 2008**. I will then present it to the Pharmacy Examining Board at its next meeting. The stipulation and order is not binding unless and until it is accepted by the board.

If you do not return the signed stipulation and order by December 9, 2008, I will file a formal complaint and initiate the hearing process. Please be aware that it is the policy of the Department to assess costs against respondents whenever any discipline is imposed. Your costs are presently $100. If we have to take this matter through a hearing, they will escalate quickly and could reach several thousand dollars.

Please call if you have any questions.

Sincerely,

Jeanette Lytle
Attorney
Division of Enforcement
608-266-9840

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	STIPULATION
MEDLINE INDUSTRIES INC.	:	LS# _____
RESPONDENT.	:	

Division of Enforcement Case # 08 PHM 037

Respondent Medline Industries Inc., by its manager Jan Hornick; and Jeanette Lytle, attorney for the Department of Regulation and Licensing, Division of Enforcement, stipulate:

1. This Stipulation is entered into as a result of a pending investigation of Respondent's licensure by the Division of Enforcement (case # 08 PHM 037). Jan Hornick represents, by her signature below, that she has authority to enter into this agreement on behalf of Respondent. Ms. Hornick, on behalf of Respondent, consents to the resolution of this investigation by stipulation.

2. Respondent's manager, Jan Hornick, understands that by signing this Stipulation she voluntarily and knowingly waives on behalf of Respondent its rights, including: the right to a hearing on the allegations against it, at which time the state has the burden of proving those allegations by a preponderance of the evidence; the right to confront and cross-examine witnesses; the right to call witnesses and to compel their attendance by subpoena; the right to testify; the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision; the right to petition for rehearing; and all other applicable rights afforded to it under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and any other provisions of state or federal law.

3. Respondent has been provided an opportunity to obtain the advice of legal counsel prior to signing this stipulation.

4. Jan Hornick agrees, on behalf of Respondent, to the adoption of the attached Final Decision and Order by the Pharmacy Examining Board. The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall be returned to the Division of Enforcement for further proceedings. In the event that this Stipulation is

not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by consideration of this attempted resolution.

6. The parties to this Stipulation agree that the attorney or other agent for the Division of Enforcement and any member of the Pharmacy Examining Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of the Respondent or its attorney, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with the Board's deliberations on the Stipulation. Additionally, any such Board advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's final decision and order is a public record and will be published in accordance with standard Department procedure.

8. The Division of Enforcement joins Jan Hornick in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.

Medline Industries Inc.

By: Jan Hornick _____ 11-24-08
Jan Hornick, manager Date
5450 West Stewart Avenue
Wausau, WI 54401

_____ _____
Jeanette Lytle Date
Attorney
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935
Madison, WI 53708-8935

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
MEDLINE INDUSTRIES INC., RESPONDENT.	:	LS # _____

Division of Enforcement Case # 08 PHM 037

The parties to this action for the purposes of Wis. Stat. § 227.53 are:

Medline Industries Inc.
5450 W. Stewart Ave.
Wausau, WI 54401

Division of Enforcement
Department of Regulation and Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

Pharmacy Examining Board
Department of Regulation & Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

PROCEDURAL HISTORY

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Pharmacy Examining Board. The Board has reviewed the attached Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. Medline Industries Inc. is duly licensed as a wholesale distributor of prescription drugs in Wisconsin (license # 45-1116). This license was first granted on June 21, 1999.

2. Respondent's most recent address on file with the Wisconsin Pharmacy Examining Board is 5450 W. Stewart Avenue, Wausau, Wisconsin 54401.

3. The Department of Regulation and Licensing conducted an unannounced inspection on May 9, 2008. The following violations were noted:

(a) The following policies were missing: Recall policy [Wis. Admin. Code § Phar 13.15(2)], Emergency plan [Wis. Admin. Code § Phar 13.15(3)], Outdated stock policy [Wis. Admin. Code § Phar 13.15(4).

(b) Respondent was storing Complete Delivery Systems (pre-packaged kits for surgeries, including various types and quantities of prescription drugs) in a warehouse it shared with another company. The CDS kits were not secured and employees of the other company had unhindered access to the kits, in violation of Wis. Admin. Code § Phar 13.10(3).

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter, pursuant to Wis. Stat. §450.10, and is authorized to enter into the attached Stipulation and Order, pursuant to Wis. Stat. § 227.44(5).

2. The conduct described in paragraph 3 above constitutes a violation of Wisconsin Administrative Code § Phar 13.10(3), Phar 13.15(2), (3) and (4), and Wis. Stat. § 450.10(1)(a)2 and 6 and subjects Respondent to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

ORDER

IT IS ORDERED:

1. Medline Industries Inc. is REPRIMANDED.

2. Respondent shall, within ninety (90) days from the date of this Order, pay a FORFEITURE in the amount of Two Thousand Dollars ($2,000.00).

3. Respondent shall, within ninety (90) days from the date of this Order, pay costs of this proceeding in the amount of One Hundred Dollars ($ 100.00). Payment shall be made payable to the Wisconsin Department of Regulation and Licensing, and mailed to:

Department Monitor
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935

Madison, WI 53708-8935
Telephone (608) 267-3817
Fax (608) 266-2264

4. In the event Respondent fails to pay the forfeiture as ordered, or in the event it fails to pay costs as ordered, Respondent's license (#45-1116) SHALL BE SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of this Order.

5. This Order is effective on the date of its signing.

Dated this __ day of _____, 2008.

PHARMACY EXAMINING BOARD

By: _____
A Member of the Board

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
MEDLINE INDUSTRIES INC., RESPONDENT.	:	LS # 0902046PHM

Division of Enforcement Case # 08 PHM 037

The parties to this action for the purposes of Wis. Stat. § 227.53 are:

Medline Industries Inc.
5450 W. Stewart Ave.
Wausau, WI 54401

Division of Enforcement
Department of Regulation and Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

Pharmacy Examining Board
Department of Regulation & Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

PROCEDURAL HISTORY

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Pharmacy Examining Board. The Board has reviewed the attached Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. Medline Industries Inc. is duly licensed as a wholesale distributor of prescription drugs in Wisconsin (license # 45-1116). This license was first granted on June 21, 1999.

2. Respondent's most recent address on file with the Wisconsin Pharmacy Examining Board is 5450 W. Stewart Avenue, Wausau, Wisconsin 54401.

3. The Department of Regulation and Licensing conducted an unannounced inspection on May 9, 2008. The following violations were noted:

(a) The following policies were missing: Recall policy [Wis. Admin. Code § Phar 13.15(2)], Emergency plan [Wis. Admin. Code § Phar 13.15(3)], Outdated stock policy [Wis. Admin. Code § Phar 13.15(4).

(b) Respondent was storing Complete Delivery Systems (pre-packaged kits for surgeries, including various types and quantities of prescription drugs) in a warehouse it shared with another company. The CDS kits were not secured and employees of the other company had unhindered access to the kits, in violation of Wis. Admin. Code § Phar 13.10(3).

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter, pursuant to Wis. Stat. §450.10, and is authorized to enter into the attached Stipulation and Order, pursuant to Wis. Stat. § 227.44(5).

2. The conduct described in paragraph 3 above constitutes a violation of Wisconsin Administrative Code § Phar 13.10(3), Phar 13.15(2), (3) and (4), and Wis. Stat. § 450.10(1)(a)2 and 6 and subjects Respondent to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

ORDER

IT IS ORDERED:

1. Mediine Industries Inc. is REPRIMANDED.

2. Respondent shall, within ninety (90) days from the date of this Order, pay a FORFEITURE in the amount of Two Thousand Dollars ($2,000.00).

3. Respondent shall, within ninety (90) days from the date of this Order, pay costs of this proceeding in the amount of One Hundred Dollars ($ 100.00). Payment shall be made payable to the Wisconsin Department of Regulation and Licensing, and mailed to:

Department Monitor
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935

Madison, WI 53708-8935
Telephone (608) 267-3817
Fax (608) 266-2264

4. In the event Respondent fails to pay the forfeiture as ordered, or in the event it fails to pay costs as ordered, Respondent's license (#45-1116) SHALL BE SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of this Order.

5. This Order is effective on the date of its signing.

Dated this 1 day of February, 2008.

PHARMACY EXAMINING BOARD

By: _____
A Member of the Board

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	05/19/2009	HI	Waipahu	Honolulu

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
PHA 2009-7-L	Hawaii Department of Commerce and Consumer Affairs

Reason/Charge
Discipline incurred in another jurisdiction

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
HI DCCA / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. agreed to enter a Consent Order for discipline incurred in another jurisdiction (Wisconsin Case #: 08 PHM 037).

Original Signature (electronic, copies or stamps not accepted)

09/02/2025
Date

BOBBI W.Y. LUM-MEW 6299
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorney for Department of Commerce
and Consumer Affairs

2009 MAY 22 A 9:24 2009 MAY 29 A 9:4

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Wholesale Prescription Drug Distributor's License of	)	PHA 2009-7-L
MEDLINE INDUSTRIES INC.,	)	SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"
Respondent.	)	

241092407

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorneys, and Respondent MEDLINE INDUSTRIES INC. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS

1. At all relevant times herein, Respondent was licensed by the Board of Pharmacy (hereinafter the "Board") as a wholesale prescription drug distributor under License Number PWD 115. The license was issued on or about October 3, 2005. The license will expire on or about December 31, 2009.

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

2. Respondent's mailing address for purposes of this action is Dianna Wolfe, Corporate Regulatory Affairs Specialist, Medline Industries, Inc., One Medline Place, Mundelein, Illinois 60060.

3. Respondent timely reported that disciplinary action had been taken against Respondent by the State of Wisconsin. Respondent had entered into a Stipulation with the State of Wisconsin's Pharmacy Examining Board. Pursuant to the terms of a Final Order, Respondent was reprimanded and ordered to pay a forfeiture in the amount of $2,000.00. This action was based on the results of an inspection which revealed that certain policies were missing and that Respondent was storing pre-packaged kits for surgeries (which included various types and quantities of prescription drugs) in a warehouse that was shared with another company. These kits were not secured and employees of the other company had access to the kits. A true and correct copy of the Stipulation and Final Decision and Order which was approved on February 4, 2009 is attached as Exhibit "1."

4. RICO alleges that Respondent was disciplined by another state for a reason provided by the licensing laws in Hawaii. Specifically, the Respondent was disciplined for professional misconduct.

5. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(13) (disciplinary action by another state) and § 461-21(a)(2) (professional misconduct). Per Hawaii Administrative Rules §§ 16-95-30(c)(6) and (9), a licensee's facility must be secure from unauthorized entry and entry into areas where prescription drugs are held must be limited to authorized personnel.

6. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein licensed as a wholesale prescription drug distributor by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the license and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's license.

6. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

7. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2009-7-L.

C. TERMS OF SETTLEMENT:

1. Administrative fine. Respondent agrees to pay a fine in the amount of ONE THOUSAND AND NO/100 DOLLARS ($1,000.00). Payment shall be made by **cashier's check, company check, or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: Bobbi Lum-Mew, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due within thirty (30) days after this Settlement Agreement is approved by the Board.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph C.1 above, Respondent's license shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the license to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new license until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become licensed again, Respondent must apply to the Board for a new license pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of wholesale prescription drug distributors in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5, C.6, C.7 and C.8 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: Mundelein, IL, 5/11/09.
(CITY) (STATE) (DATE)

MEDLINE INDUSTRIES INC.

By: [signature]
Its Pres. of QAIRA

DATED: Honolulu, Hawaii, MAY 19 2009.

[signature]
DARIA A. LOY-GOTO
BOBBI W.Y. LUM-MEW
Attorneys for Department of Commerce and Consumer Affairs

IN THE MATTER OF THE WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR'S LICENSE OF MEDLINE INDUSTRIES INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER: PHA 2009-7-L; EXHIBIT "1"

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

June 18, 2009
DATE

ELWIN D.H. GOO
Chairperson

MARK E. BROWN
Vice-Chairperson

LAURIE H. Y. KAWAMURA

KENT KIKUCHI

KARL H. MIYAMOTO

PATRICK ADAMS

STANLEY M. CHOW

PVL 05/20/08

STATE OF Illinois)
) SS.
COUNTY OF Lake)

On this 11 day of May, 2009, before me personally appeared Leo V Simms, to me known to be the person described, and who executed the foregoing instrument on behalf of Mallco Industries as President CEO/CFO, and acknowledged that he/she executed the same as his/her free act and deed.

OFFICIAL SEAL
SUSAN MILLER
Notary Public - State of Illinois
My Commission Expires Jul 16, 2011

Name: Susan Miller
Notary Public, State of IL

My Commission expires: July 16, 2011

2009

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
MEDLINE INDUSTRIES INC., RESPONDENT.	:	LS # 0902046PHM

Division of Enforcement Case # 08 PHM 037

The parties to this action for the purposes of Wis. Stat. § 227.53 are:

Medline Industries Inc.
5450 W. Stewart Ave.
Wausau, WI 54401

Division of Enforcement
Department of Regulation and Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

Pharmacy Examining Board
Department of Regulation & Licensing
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708-8935

PROCEDURAL HISTORY

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Pharmacy Examining Board. The Board has reviewed the attached Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. Medline Industries Inc. is duly licensed as a wholesale distributor of prescription drugs in Wisconsin (license # 45-1116). This license was first granted on June 21, 1999.

EXHIBIT "1"

2. Respondent's most recent address on file with the Wisconsin Pharmacy Examining Board is 5450 W. Stewart Avenue, Wausau, Wisconsin 54401.

3. The Department of Regulation and Licensing conducted an unannounced inspection on May 9, 2008. The following violations were noted:

(a) The following policies were missing: Recall policy [Wis. Admin. Code § Phar 13.15(2)], Emergency plan [Wis. Admin. Code § Phar 13.15(3)], Outdated stock policy [Wis. Admin. Code § Phar 13.15(4).

(b) Respondent was storing Complete Delivery Systems (pre-packaged kits for surgeries, including various types and quantities of prescription drugs) in a warehouse it shared with another company. The CDS kits were not secured and employees of the other company had unhindered access to the kits, in violation of Wis. Admin. Code § Phar 13.10(3).

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter, pursuant to Wis. Stat. §450.10, and is authorized to enter into the attached Stipulation and Order, pursuant to Wis. Stat. § 227.44(5).

2. The conduct described in paragraph 3 above constitutes a violation of Wisconsin Administrative Code § Phar 13.10(3), Phar 13.15(2), (3) and (4), and Wis. Stat. § 450.10(1)(a)2 and 6 and subjects Respondent to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

ORDER

IT IS ORDERED:

1. Medline Industries Inc. is REPRIMANDED.

2. Respondent shall, within ninety (90) days from the date of this Order, pay a FORFEITURE in the amount of Two Thousand Dollars ($2,000.00).

3. Respondent shall, within ninety (90) days from the date of this Order, pay costs of this proceeding in the amount of One Hundred Dollars ($ 100.00). Payment shall be made payable to the Wisconsin Department of Regulation and Licensing, and mailed to:

Department Monitor
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935

Madison, WI 53708-8935
Telephone (608) 267-3817
Fax (608) 266-2264

4. In the event Respondent fails to pay the forfeiture as ordered, or in the event it fails to pay costs as ordered, Respondent's license (#45-1116) SHALL BE SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of this Order.

5. This Order is effective on the date of its signing.

Dated this 4 day of February, 2009.

PHARMACY EXAMINING BOARD

By: Gregory C. Kelly
A Member of the Board

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
MEDLINE INDUSTRIES INC. RESPONDENT.	:	STIPULATION LS#0902046PHM

Division of Enforcement Case # 08 PHM 037

Respondent Medline Industries Inc., by its manager Jan Hornick; and Jeanette Lytle, attorney for the Department of Regulation and Licensing, Division of Enforcement, stipulate:

1. This Stipulation is entered into as a result of a pending investigation of Respondent's licensure by the Division of Enforcement (case # 08 PHM 037). Jan Hornick represents, by her signature below, that she has authority to enter into this agreement on behalf of Respondent. Ms. Hornick, on behalf of Respondent, consents to the resolution of this investigation by stipulation.

2. Respondent's manager, Jan Hornick, understands that by signing this Stipulation she voluntarily and knowingly waives on behalf of Respondent its rights, including: the right to a hearing on the allegations against it, at which time the state has the burden of proving those allegations by a preponderance of the evidence; the right to confront and cross-examine witnesses; the right to call witnesses and to compel their attendance by subpoena; the right to testify; the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision; the right to petition for rehearing; and all other applicable rights afforded to it under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and any other provisions of state or federal law.

3. Respondent has been provided an opportunity to obtain the advice of legal counsel prior to signing this stipulation.

4. Jan Hornick agrees, on behalf of Respondent, to the adoption of the attached Final Decision and Order by the Pharmacy Examining Board. The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall be returned to the Division of Enforcement for further proceedings. In the event that this Stipulation is

not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by consideration of this attempted resolution.

6. The parties to this Stipulation agree that the attorney or other agent for the Division of Enforcement and any member of the Pharmacy Examining Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of the Respondent or its attorney, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with the Board's deliberations on the Stipulation. Additionally, any such Board advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's final decision and order is a public record and will be published in accordance with standard Department procedure.

8. The Division of Enforcement joins Jan Hornick in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.

Medline Industries Inc.

By: Jan Hornick 11-24-08

Jan Hornick, manager
5450 West Stewart Avenue
Wausau, WI 54401

Date

12/10/08

Jeanette Lytle
Attorney
Division of Enforcement
Department of Regulation and Licensing
P.O. Box 8935
Madison, WI 53708-8935

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	03/19/2010	MO	Kansas City	Jackson
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2010-002994		Colorado State Board of Pharmacy		
Reason/Charge				
Conditional License				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
CO Board of Pharmacy / Medline Industries, Inc.			Administrative Action	
Name of Business/Industry/Entity				
Medline Industries, Inc.				

Provide explanation below:

Medline Industries, Inc. distribution center at 1401 N. Universal Ave, Kansas City, MO 64120 applied for a Colorado Out-of-State Wholesaler license. The CO Board of Pharmacy issued a conditional license until the facility's MO probation period ended. (See Case 2003031660 above). Medline informed the CO Board when the MO probationary period was completed. Upon completion of probation, the Board issued a full license.

Corrective Actions:
Medline successfully completed terms of probation in MO and CO.

Original Signature (electronic, copies or stamps not accepted)

09/02/2026
Date

Dora
Department of Regulatory Agencies

Division of Registrations
Rosemary McCool
Director

State Board of Pharmacy
Wendy Anderson
Program Director

Bill Ritter, Jr.
Governor

Barbara J. Kelley
Executive
Director

March 24, 2010

MedLine Industries, Inc.
Attn: Scott C. Barbour, Designated Representative
1401 N. Universal Ave.
Kansas City, MO 64120

RE: Stipulation and Final Agency Order
Case #2010-2994

IN THE MATTER OF DISCIPLINARY RPOCEEDINS REGARDING THE LICENSE TO PRACTICE AS A OUT-OF-STATE WHOLESALER IN THE STATE OF COLORADO OF MEDLINE INDUSTRIES, INC.,

Dear Mr. Barbour:

Enclosed you will find a copy of the fully executed Stipulation and Final Agency Order (Stip/FAO) n the above mentioned matter, which became effective March 19, 2010.

Accordingly, and pursuant to Conditional Registration, item 9, of the Stip/FAO, MedLine Industries, Inc., at the above listed location, has been issued out-of-state prescription drug wholesaler registration #7713, with conditions, effective March 23, 2010.

Medline Industries, Inc., Colorado out-of-state wholesaler registration #7713 shall be probationary pending the Colorado State Board of Pharmacy's receipt of a request for discharge from Medline Industries, Inc., which must include documentation showing Medline Industries, Inc.'s release from the terms and conditions of the Missouri Settlement Agreement effective 8/3 05.

If you have any questions, or require additional information, please feel free to contact me at (303) 894-2989.

Respectfully,

FOR THE COLORADO STATE BOARD OF PHARMACY

Tia Johnson
Complaint Analyst
Enclosure
cc: Beth Thompson, Vice President, Regulatory Affairs, Medline Industries, Inc.
John Steele, Settlement Specialist, Office of Expedited Settlement
Jazell Carter, Licensing Specialist, Office of Licensing
File

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2010-002994

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE LICENSE TO PRACTICE AS A OUT-OF-STATE WHOLESALER IN THE STATE OF COLORADO OF MEDLINE INDUSTRIES, INC.,

Wholesaler Applicant.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Medline Industries, Inc. ("Wholesaler Applicant") to resolve all matters pertaining to Board Case Number 2010-002994 as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Wholesaler Applicant, its application for registration as an out-of-state wholesaler and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S.

2. Wholesaler Applicant admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

3. Wholesaler Applicant entered into a Settlement Agreement with the Missouri State Board of Pharmacy, which was effective on August 3, 2005 ("Missouri Settlement Agreement").

4. In the Missouri Settlement Agreement, Wholesaler Applicant was placed on probation for five (5) years for various violations of Missouri state and federal law involving recordkeeping, storage of prescription drugs, change of location without informing the Missouri Board of Pharmacy, lack of a policy and procedure manual, and distribution of prescription drugs under a lapsed registration.

5. Wholesaler Applicant's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes:

12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(III) Any state or federal law pertaining to drugs.

12-22-125.2. Disciplinary actions.

(1) The board may deny or discipline an applicant, licensee, or registrant when the board determines that such applicant, licensee, or registrant has engaged in activities that are grounds for discipline.

6. On January 14, 2010, Wholesaler Applicant submitted an out-of-state wholesaler application, which application was denied by the Board.

7. On March 1, 2010, Wholesaler Applicant submitted a written request asking that the Board accept its application by granting a conditional license.

8. The Board finds and concludes, and Wholesaler Applicant agrees, that based upon Wholesaler Applicant's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances as a condition of its registration as an out-of-state wholesaler.

DISPOSITION

Conditional Registration / Probation / Compliance / Terms

9. **Conditional Registration.** Wholesaler Applicant shall be granted a registration as an out-of-state wholesaler upon execution of this Final Agency Order and satisfaction of the terms and conditions set forth herein.

10. **Probation.** Wholesaler Applicant's registration shall be placed on probation for a period of time equal to the time of probation remaining under the Missouri Settlement Agreement. Credit toward satisfying the period of probation under this Final Agency Order shall be given only during such periods of time that Respondent is in total compliance with all provisions of this Final Agency Order and the Missouri Settlement Agreement.

11. **Compliance.** Wholesaler Applicant shall at all times remain in compliance with §§12-22-801, *et seq.* C.R.S. and shall not at any time distribute prescription drugs into Colorado without being registered as an out-of-state wholesaler in the State of Colorado at the time of distribution.

12. **Other Requirements.** Wholesaler Applicant acknowledges and agrees that, as a condition of this Final Agency Order and probation, Wholesaler Applicant shall:

    a. promptly pay all Wholesaler Applicant's own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

13. **Discharge.** Discharge from the requirements of this Final Agency Order must be requested in writing by Wholesaler Applicant. The Board will consider any request for discharge during the ordinary course of business. In any request for discharge it shall be Wholesaler Applicant's sole responsibility to establish, through written and other documentation, that Wholesaler Applicant has met all terms and conditions of this Final Agency Order and, in addition, has been released from probation by the Missouri Board of Pharmacy under the Missouri Settlement Agreement. Wholesaler Applicant's probation under this Final Agency Order shall continue until formally discharged by the Board by way of Board order.

14. **Advisements and Waivers.** Wholesaler Applicant enters into this Final Agency Order freely and voluntarily, whether or not Wholesaler Applicant has consulted with legal counsel. Wholesaler Applicant acknowledges its understanding that it has the following rights:

    a. To have a formal notice of hearing and charges served upon it;
    b. To respond to said formal notice of charges;
    c. To have a formal disciplinary hearing pursuant to §12-22-125, C.R.S.; and
    d. To appeal this Board order.

    Wholesaler Applicant freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

15. **Acknowledgments.** The undersigned authorized agent of Wholesaler Applicant has read this Final Agency Order in its entirety and acknowledges, whether or not Wholesaler Applicant has consulted with legal counsel, that Wholesaler Applicant

understands the legal consequences and agrees that none of the terms or conditions herein are unconscionable.

16. **Violations**. Time is of the essence to this Final Agency Order. It is the responsibility of Wholesaler Applicant to take all appropriate steps to comply fully with this Final Agency Order. Wholesaler Applicant acknowledges and agrees that any violation of this Final Agency Order may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Wholesaler Applicant to comply with all terms and conditions of this Final Agency Order.

17. **Integration and Severability**. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

18. **Public Record**. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

19. **Effective Date**. This Final Agency Order shall become effective upon signature of a Board member or representative.

ACCEPTED AND AGREED BY

Dana N. Simmons

Dated: 3/12/10

Authorized Agent of Wholesaler Applicant

Subscribed and sworn to by Dana N. Simmons, in his/her capacity as an authorized agent of Medline Industries, Inc., before me in the County of Lake, State of Illinois, this 12 day of March, 2010.

OFFICIAL SEAL
SUSAN MILLER
Notary Public - State of Illinois
My Commission Expires Jul 16, 2011

Susan Miller

Notary Public

My commission expires: 7-16-2011

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 19th day of January, 2010.

State Board of Pharmacy

BY: Wendy Anderson

Wendy Anderson
Program Director

CERTIFICATE OF MAILING

This is to certify that I have duly mailed the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 5th day of March 2010, addressed as follows:

Medline Industries, Inc.
Attn: Scott C. Barbour, Designated Representative
1401 N. Universal Ave.
Kansas City, MO 64120

Beth Thompson
Vice President, Regulatory Affairs
Medline Industries, Inc.
1 Medline Pl.
Mundelein, IL 60060

John C. Steele

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 24th day of March 2010, addressed as follows:

Medline Industries, Inc.
Attn: Scott C. Barbour, Designated Representative
1401 N. Universal Ave.
Kansas City, MO 64120

Beth Thompson
Vice President, Regulatory Affairs
Medline Industries, Inc.
1 Medline Pl.
Mundelein, IL 60060

Agent of the Board

Dora
Department of Regulatory Agencies

Division of Registrations
Rosemary McCool
Director

State Board of Pharmacy
Wendy Anderson
Program Director

Bill Ritter, Jr.
Governor

Barbara J. Kelley
Executive
Director

August 25, 2010

MedLine Industries, Inc.
Attn: Scott C. Barbour, Designated Representative
1401 N. Universal Ave.
Kansas City, MO 64120

RE: Stipulation and Final Agency Order (Stip/FAO), effective 3/19/10
Case #2010-2994

Dear Mr. Barbour:

Staff for the Colorado State Board of Pharmacy ("Board") has reviewed the material concerning Medline Industries' request for release from the terms and conditions of the above listed Stip/FAO effective 3/19/10.

After due consideration, and pursuant to Board Policy 10-6, staff for the Board released Medline Industries, Inc., from the terms and conditions of the 3/19/10 Stip/FAO, and restored its out-of-state prescription drug wholesaler registration #7713 to unencumbered status, effective 8/25/10.

Your cooperation during the pendency of this matter is sincerely appreciated.

Sincerely,

FOR THE COLORADO STATE BOARD OF PHARMACY

Wendy L. Anderson
Program Director

cc: Beth Thompson, Vice President, Regulatory Affairs, Medline Industries, Inc.
File

Policy Number: 10-6

Title: Delegation of Authority to Program Director or Section Director

Date Issued: 11/16/2006

Dates Revised: 8/21/08, 10/16/08, 9/17/09, 1/21/10, 7/16/2010

PURPOSE: To clarify the authority which has been delegated to the Program Director, Section Director, or his/her designee

---

POLICY: The Board of Pharmacy has delegated to the Program Director, Section Director or his/her designee the authority to:

1. Sign Stipulations and Final Agency Orders ("Stipulations") and final orders issued subsequent to initial decisions entered after hearings held by administrative law judges ("Final Board Orders") on its behalf.
2. Issue Final Board Orders on its behalf when no exceptions are filed to the initial decision, the statutorily allowed time frame for the filing of exceptions has passed, the recommended sanction from the Administrative Law Judge is the same as that sought by the Board, and no further decisions are required by the Board.
3. Process reports of settlement of malpractice claims in the same manner as signed complaints are handled.
4. Accept, on the Board's behalf, practice and treatment monitoring reports and any other such reports submitted as required by the Stipulation or Final Board Order, provided such reports are in compliance with the terms of the Stipulation or Final Board Order.
5. Initiate complaints and issue 30-day letters to licensees or registrants currently under Stipulation or Final Board Order if, in the opinion of the Program Director or his/her designee, the licensee or registrant has failed to comply with any of the terms of his or her stipulation.
6. Sign Suspension Orders as required by the Child Support Enforcement Program.
7. Subpoena documents and gather information in order to assist the Board in carrying out its duties.
8. Approve practice monitors for licensees and registrants as required pursuant to Stipulations or Final Board Orders.
9. Sign suspension orders on its behalf.
10. Sign cease and desist orders on its behalf.
11. Perform the initial review of complaints relating to the practice of licensees or registrants under the Board's jurisdiction and to issue 30-day letters relating to the complaints.
12. Initiate complaints and issue 30-day letters where otherwise authorized by the Board.
13. Determine non-substantive procedural matters relating to the rendering of initial decisions, including, but not limited to, granting extensions of time for the filing of exceptions, and granting requests for oral argument.
14. Perform additional delegated duties as set forth in Board policies.

15. Make referrals for assessment to the Pharmacy Peer Assistance Diversion Program.

16. Suspend the licenses of individuals under Stipulation or Final Board Order if licensee is required to participate in the Pharmacy Peer Assistance Diversion Program as a requirement of his/her Stipulation or Final Board Order and fails to comply with his/her contract with the Rehabilitation Evaluation Committee. The Program Director or his/her designee may lift the Board suspension on such licenses when the licensee has resumed compliance.

17. Release licensees and registrants from the terms of their Stipulations or Final Board Orders provided the licensee submits satisfactory evidence of completion of all terms of the Stipulation or Final Board Order. The Program Director or his/her designee, at his/her discretion, may refer any request for discharge to the Board for review.

18. Deny requests from licensees and registrants for discharge from the terms of Stipulations or Final Board Orders when the licensee or registrant has not completed the terms of the Stipulation or Final Board Order. Requests for early discharge from Stipulations and Final Board Orders shall be denied.

19. Suspend the licenses or registrations of facilities which have been ordered to pay a fine pursuant to a Stipulation or Final Board Order and fail to remit the required payment. In the event the licensee or registrant is to pay the fine in installments, the Program Director or his/her designee may suspend the license or registration if the licensee or registrant fails to remit a required payment. The Program Director or his/her designee may lift the Board suspension on such licenses or registrations when the licensee or registrant has come into compliance with fine requirements.

20. Enter, on its behalf, written agreements with public or private entities whereby the Board may provide information from the Electronic Prescription Drug Monitoring Program that does not identify a patient, prescriber, or dispenser of a prescription drug. Such agreements may only be entered into for the purposes of bona fide research or education pursuant to CRS 12-22-705(5).

21. Notice, on its behalf, proposed rules or proposed amendments or deletions to rules for a hearing before the board pursuant to CRS 24-4-103.

22. In the absence of additional exculpatory evidence or information not previously before the board, reject any counteroffer from respondents with cases at the Office of Expedited Settlement that is not within the board's settlement parameters.

23. Issue on its behalf, the "Board Procedural Order regarding Review of Initial Decision" upon receipt of an Initial Decision from an Administrative Law Judge at the Office of Administrative Courts.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	7/18/2014	NY	Middletown	Orange

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
27278	NY State Education Department- Board of Pharmacy

Reason/Charge
Discipline incurred in another jurisdiction

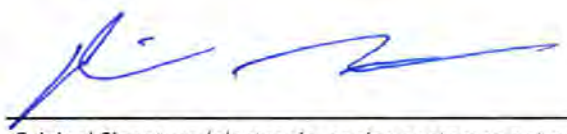
Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
NY Board of Pharmacy / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. agreed to enter a Consent Order for discipline incurred in another jurisdiction (FL No. 2007-37412, LA No. 2008006, and WI No. 08 PHM 037).

Corrective Actions:
See corrective actions for FL No. 2007-37412, LA No. 2008006, and WI No. 08 PHM 037.



Original Signature (electronic, copies or stamps not accepted)

07/02/2024

Date

THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK

OFFICE OF PROFESSIONAL DISCIPLINE
(212) 921-3872/3873

1411 BROADWAY - TENTH FLOOR
NEW YORK, NEW YORK 10018

July 18, 2014

Medline Industries Inc., Pharmacy Wholesaler
3301 Route 6
Middletown, NY 10940

Re: License No. 028250

Dear Sir or Madam:

Enclosed please find Order No. 27278. This letter will explain when the Order regarding the above respondent goes into effect.

If the penalty imposed by the Order is an annulment, revocation, surrender, or an actual suspension (suspension which is not wholly stayed) of your license, you must deliver your license and registration to this Department within ten (10) days after the date of this letter.

In the event you are personally served with the Order, the Order is effective as of the date of the personal service. In the event you are served by certified mail and are not personally served with the Order, the Order is effective five (5) days after the date of this letter. The Order will take effect as indicated in this letter, even if you fail to meet the time requirement of delivering your license and registration to this Department.

If the penalty imposed by the Order is a revocation or a surrender of your license, you may, pursuant to Rule 24.7 (b) of the Rules of the Board of Regents, a copy of which is attached, apply for restoration of your license after three years have elapsed from the effective date of the Order and the penalty. Please be advised that said application is not granted automatically.

The record and reports of a disciplinary proceeding or resulting voluntary settlement shall be considered matters of public information unless specifically excepted by law or applicable rule or regulation.

Very truly yours,

DONALD DAWSON
Director of Investigations
By: Ariana Miller
ARIANA MILLER
Supervisor

LJC/AM/nbm
Enclosure
CERTIFIED MAIL – RRR
cc: Judith A. Eisen, Esq.
Garfunkel Wild, P.C.
111 Great Neck Road
Great Neck, NY 11021

C201406

VOTE AND ORDER

MEDLINE INDUSTRIES INC.

CALENDAR NO. 27278

NEW YORK STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE
STATE BOARD OF PHARMACY
----------X

IN THE MATTER

of the

Disciplinary Proceeding

against

MEDLINE INDUSTRIES INC.

which is currently registered to operate as a pharmacy wholesaler in the State of New York.
----------X

APPLICATION FOR CONSENT ORDER

CAL. NO. 27278

LARA N. SIMMONS states:

That I am President, Quality Assurance and Regulatory Affairs of **MEDLINE INDUSTRIES INC.**, hereinafter referred to as the Respondent, and make this application on Respondent's behalf.

That on or about February 21, 2007 Respondent was registered to operate as a pharmacy wholesaler in the State of New York, having been issued Registration No. 028250 by the New York State Education Department.

Respondent is currently registered with the New York State Education Department to operate as a pharmacy wholesaler in the State of New York from an address at: 3301 Route 6, Middletown, New York 10940.

Respondent has been charged with one (1) specification of professional misconduct, a copy of which is annexed hereto, made a part hereof, and marked as Exhibit "A". Respondent admits

guilt to the aforesaid specification of professional misconduct, charging it with having been found guilty of improper professional practice or professional misconduct by a duly authorized professional disciplinary agency of another state where the conduct upon which the finding was based would, if committed in New York State, constitute professional misconduct under the laws of New York State (findings of misconduct committed during the period 2008 to 2009 by three separate states which, if committed in New York, would constitute professional misconduct under the Education Law and Commissioner's Regulations).

Respondent hereby agrees to the penalty that it pay a fine in the amount of five thousand dollars ($5,000.00), said fine to be paid by certified or cashier's check, made payable to the order of the New York State Education Department, to be delivered to the Director, Office of Professional Discipline, 1411 Broadway, 10th Floor, New York, New York 10018-3496, within thirty (30) days after the effective date of the Order to be issued in this matter.

Respondent hereby makes this application to the Board of Regents and requests that it be granted.

Respondent understands that in the event that the Board of Regents denies the application, nothing contained herein shall be binding upon it or construed to be an admission of any act of misconduct alleged or charged against it. Such application shall

not be used against it in any way and shall be kept in strict confidence during the pendency of the disciplinary proceeding, and such denial by the Board of Regents shall be without prejudice to the continuance of the disciplinary proceeding and the final determination by the Board of Regents pursuant to the provisions of the Education Law.

Respondent agrees that in the event the Board of Regents grants its application, as set forth herein, an Order may be issued in accordance with the same. Respondent understands that if and when the Board of Regents grants this application, the entire application shall become a matter of public record.

No promises of any kind were made to Respondent. Respondent is making this application of its own free will and accord and not under duress, compulsion, or restraint of any kind or manner.

LARA N. SIMMONS

EXHIBIT "A"

MEDLINE INDUSTRIES INC.

SPECIFICATION OF PROFESSIONAL MISCONDUCT

Respondent is charged with having been found guilty of improper professional practice or professional misconduct by a duly authorized professional disciplinary agency of another state where the conduct upon which the finding was based would, if committed in New York State, constitute professional misconduct under the laws of New York State, within the purview and meaning of New York Education Law section 6509(5)(b), in that:

(a) On or about September 26, 2008, the Department of Health of the State of Florida, a duly authorized disciplinary agency of said state, issued a Final Order against the Respondent (Case No. 2007-11783);

(b) The conduct upon which said Final Order was based was that (1) Respondent failed to provide in a timely manner documents that were requested and (2) Respondent sold or transferred a legend drug to a person who was not authorized under the law of the jurisdiction in which the person received the drug to purchase or possess legend drugs from the Respondent;

(c) Said conduct, if committed in New York, would constitute professional misconduct under Section 6509(13) of the Education Law and Part 63.6(c)(5)

of the Commissioner's Regulations;

(d) On or about May 1, 2008, the Louisiana Board of Wholesale Drug Distributors, a duly authorized disciplinary agency of Louisiana, issued a Consent Order against the Respondent (Administrative Case No. 2008006);

(e) The conduct upon which said Consent Order was based was that Respondent failed to maintain current customer license documents and/or a current customer listing on-site;

(f) Said conduct, if committed in New York, would constitute professional misconduct under Part 63.6(c)(5) of the Commissioner's Regulations;

(g) On or about February 4, 2009, the Wisconsin Pharmacy Examining Board, a duly authorized disciplinary agency of Wisconsin, issued a Final Decision and Order (Case #08-PHM 037);

(h) The conduct upon which said Decision and Order was based was that when Respondent was inspected by the Wisconsin Department of Regulation and Licensing, it was found that certain policies were missing and that it was storing prescription drugs in a warehouse it shared with another company;

(i) Said conduct, if committed in New York, would constitute professional misconduct under Part 63.6(c)(4) of the Commissioner's Regulations and

Title 21, Section 205.50, Code of Federal Regulations (CFR).

NEW YORK STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE
STATE BOARD OF PHARMACY

IN THE MATTER

of the

Disciplinary Proceeding

against

MEDLINE INDUSTRIES INC.

which is currently registered to operate as a pharmacy wholesaler in the State of New York.

APPLICATION FOR CONSENT ORDER

CAL. NO. 27278

The undersigned agree to the above statement and to the proposed penalty based on the terms and conditions thereof.

MEDLINE INDUSTRIES INC.

Dated: 2/14, 2014

Respondent

BY: Lara N Simmons

Lara N. Simmons, President, Quality Assurance and Regulatory Affairs

Dated: 2/18, 2014

Judith Eisen

Attorney for Respondent

Dated: 2/27, 2014

Member, State Board of Pharmacy

Dated: 3/6, 2014

Executive Secretary
State Board of Pharmacy

Dated: 4/23, 2014

Director
Office of Professional Discipline

The undersigned, a member of the Board of Regents who has been designated by the Chairman of the Regents Committee on Professional Practice to review this Application for a Consent Order, has reviewed said Application and recommends to the Board of Regents that the Application be granted.

Dated: 5/7, 2014

Member, Board of Regents

:ds

Section 24.7 (b) For individuals served prior to June 20, 1997 with an order of revocation, acceptance of surrender, or denial of an application for restoration or reinstatement by vote of the Board of Regents, at least one year shall have elapsed from the date of such service for the acceptance by the department of a petition to the Board of Regents for restoration of a license or certificate, except that a period of time during which the license was suspended during the pendency of the discipline proceeding may reduce the one-year waiting period. For individuals served on or after June 20, 1997 with an with an order of revocation, acceptance of surrender, or denial of an application for restoration or reinstatement by vote of the Board of Regents, at least three years shall have elapsed from the date of such service for the acceptance by the department of a petition to the Board of Regents for restoration of a license or certificate, except that a period of time during which the license was suspended during the pendency of the discipline proceeding may reduce the three-year waiting period. This section shall not apply to restoration of licenses which have been temporarily surrendered pursuant to Education Law, section 6510-b, or Public Health Law, section 230(13).

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	01/06/2021	IL	Libertyville	Lake

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
A-2020-0054	Ohio Board of Pharmacy

Reason/Charge
Customer License

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Ohio Board of Pharmacy / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. distribution center at 1501 Harris Rd Libertyville, IL 60048 (OH License #01-1985050) entered into a settlement agreement with the Ohio Board of Pharmacy for the sale of dangerous drugs to an unlicensed entity. Medline maintained a current and valid DEA license on file rather than the correct Terminal Distributor Dangerous Drugs license (TDDD). The facility's TDDD license expired at the time of the sale. Case resolved via Settlement Agreement effective 01/06/2021.

Corrective Actions:
Medline updated its customer license requirements for Ohio customers. Medline completed a review of all Ohio customers to verify the correct license type was on file and implemented increased verification checks of Ohio licenses.

Original Signature (electronic, copies or stamps not accepted)

09/02/2026
Date

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE No. A-2020-0054
I-2019-0972-B

Medline Industries, Inc.
c/o Willis Ingalls
1501 Harris Road
Libertyville, IL 60048

License No. 01-1985050

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Medline Industries, Inc. for the purpose of resolving all issues between the parties relating to the Board investigation of a selling dangerous drugs to an unlicensed entity. Together, the Board and Medline Industries are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Medline Industries, LLC, has an active WDDD license with the Board under license number 01-1985050, which lists Willis Ingalls as the Responsible Person.

FACTS

1. The Board initiated an investigation of Medline Industries, WDDD license number 01-1985050, related to the sale of dangerous drugs to an unlicensed entity.

2. On or about December 3, 2020, the Board sent a Notice of Opportunity for Hearing to Medline Industries, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Medline Industries neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated December 3, 2020, however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Medline Industries agrees to pay to the Board a monetary penalty the amount of $250.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. Medline Industries agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

5. Medline Industries agrees to comply with all federal and state requirements related to Wholesale Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Medline Industries of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Medline Industries by the Board and will NOT discharge Medline Industries from any obligation under the terms of this Agreement.

6. Medline Industries agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

7. Medline Industries understands that it has the right to be represented by counsel for review and execution of this agreement.

8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Medline Industries will operate.

9. Medline Industries expressly waives its opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to appeal.

10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Willis A. Ingalls — 1-5-21

Willis Ingalls, on behalf of,
Medline Industries, Respondent — **Date of Signature**

Attorney for Respondent (if applicable) — **Date of Signature**

Jennifer M. Rudell, RPh — 1-6-2021

Jennifer M. Rudell, RPh, President,
State of Ohio Board of Pharmacy — **Date of Signature**

1-6-2021

Henry Appel, Ohio Assistant Attorney General — **Date of Signature**

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	06/28/2021	IL	Libertyville	Lake

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
21-L-0048	Alabama Board of Pharmacy

Reason/Charge
Discipline incurred in another jurisdiction

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Alabama Board of Pharmacy / Medline Industries, Inc.	Administrative Action

Name of Business/Industry/Entity
Medline Industries, Inc.

Provide explanation below:

Medline Industries, Inc. distribution center at 1501 Harris Rd Libertyville, IL 60048 (AL Non-Resident Permit #193718) was fined for discipline incurred in another jurisdiction (OH A-2020-0054).

Original Signature (electronic, copies or stamps not accepted)

09/02/2026
Date

Alabama Board of Pharmacy
111 Village Street
Birmingham AL 35242

USPS CERTIFIED MAIL



9414 8118 9876 5809 1318 98

MEDLINE INDUSTRIES, INC.
1501 HARRIS ROAD
LIBERTYVILLE IL 60048



$5.86 US POSTAGE
FIRST-CLASS
Jun 28 2021
Mailed from ZIP 35242
1 oz First-Class Mail Letter

11923276



062S0012913542

FO - 21-L-0048 193718

0922

DocuSign Envelope ID: 7F8AA924-F79F-4BC6-A7E1-B16F9D238852

THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	
MEDLINE INDUSTRIES, INC.	)	BOARD OF PHARMACY
	)	
Wholesale Distributor Permit No. 193718	)	CASE NO: 21-L-0048

FINAL ORDER

On June 15, 2021, this cause came before the Alabama State Board of Pharmacy (hereinafter also referred to as the "Board"), on a Complaint against Medline Industries, Inc. (hereinafter also referred to as the "Respondent"). Evidence having been adduced thereon, the Board has determined that the following Findings of Fact and Conclusions of Law are supported by the preponderant weight of evidence and law.

Findings of Fact

1. The Respondent is a wholesale distributor permitted by this Board under Permit No. 193718. (Board Exhibit One)

2. The Respondent was properly notified of the charges on March 9, 2021. The Respondent did not appear at the scheduled hearing before the Board and was not represented by counsel at such hearing. (Board Exhibit One and Two)

3. The Respondent made no objection to the timeliness of the Notice of Hearing or the specificity of the Statement of Charges.

4. The Respondent violated Board Rules 680-X-2.23, 680-X-2.23(3), 680-X-2.23(3)(k)(1), 680-X-2.23(3)(k)(2), and 680-X-2.23(3)(k)(3) and Code of Alabama (1975), § 34-23-32 based upon Respondent's underlying conduct in its entry into a Settlement Agreement with the State of Ohio Board of Pharmacy dated January 6, 2021 (Attached) in which discipline was

DocuSign Envelope ID: 7F8AA924-F79F-4BC6-A7E1-B16F9D238852

imposed. In that Settlement Agreement, Respondent admitted that the State of Ohio Board of Pharmacy had evidence sufficient to sustain the allegations that Respondent made five (5) illegal sales of dangerous drugs to Columbus Podiatry & Surgery, Inc.

Conclusions of Law

1. The Alabama State Board of Pharmacy has jurisdiction of this cause pursuant to Code of Alabama (1975), § 34-23-,32 Code of Alabama (1975), § 34-23-92(12), and Code of Alabama (1975), § 41-22-12.

2. The Respondent was properly notified of the charges, failed to appear and was not represented by counsel at the administrative hearing. The Respondent did not contest the matter in any manner.

3. The Respondent made no objection to the timeliness of the Notice of Hearing or the specificity of the Statement of Charges.

4. The Respondent is due to be fined $500.00 in that it is guilty of violating Board Rules 680-X-2.23, 680-X-2.23(3), 680-X-2.23(3)(k)(1), 680-X-2.23(3)(k)(2), and 680-X-2.23(3)(k)(3) and Code of Alabama (1975), § 34-23-32 in regard to its conduct involving illegal sales of dangerous drugs which resulted in discipline/Settlement Agreement dated January 6, 2021 with the State of Ohio Board of Pharmacy.

ORDER

In accordance with the foregoing Findings of Fact and Conclusions of Law, it is hereby ORDERED as follows:

DocuSign Envelope ID: 7F8AA924-F79F-4BC6-A7E1-B16F9D238852

1. The Respondent is guilty as charged in Count One as contained in the Statement of Charges and Notice of Hearing and is hereby fined a total of Five Hundred ($500.00) Dollars.

2. The disciplinary fine of Five Hundred ($500.00) Dollars is due and payable to the Board within thirty (30) days of the date of this Final Order.

DONE and ORDERED, this 28th day of June, 2021.

Brenda R. Denson, Pharm.D., President
Alabama State Board of Pharmacy

Copies to:
Medline Industries, Inc.
Ms. Donna C. Yeatman, R. Ph., Executive Secretary
Mr. James S. Ward, Esq.
Mr. James F. Hampton, Esq.
Mr. Vance L. Alexander, Esq.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	11/01/2022	OH	West Jefferson	Madison
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
A-2022-0333		Ohio Board of Pharmacy		
Reason/Charge				
Customer Licenses				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Ohio Board of Pharmacy / Medline Industries, LP			Administrative Action	
Name of Business/Industry/Entity				
Medline Industries, LP				

Provide explanation below:

Medline Industries, LP distribution center at 1040 Enterprise Parkway South, West Jefferson, OH 43162 (OH License #01-30000190) entered a settlement agreement with the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file instead of the correct Terminal Distributor Dangerous Drugs license (TDDD). The TDDD license was added in May 2022. During the period of July 2021 to March 2022, the customer's TDDD license lapsed, and Medline shipped the customer product under the valid practitioner license. Case resolved via Settlement Agreement effective 11/01/2022.

Corrective Actions:
Medline updated customer licensing requirements for Ohio customers following OH Case # A-2020-0054. The shipments in this matter occurred while Medline was in the process of reviewing and updating all Ohio customer licenses. Medline licensing staff were also provided with additional training on Ohio license requirements.

Original Signature (electronic, copies or stamps not accepted)

09/02/2026
Date

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. A-2022-0333
I-2022-0624

Medline Industries, LP
c/o James Eveland
1040 Enterprise Parkway South
West Jefferson, OH 43162

License No. 01-30000190

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Medline Industries, LP, for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of dangerous drugs to an unlicensed entity. Together, the Board and Medline Industries, LP are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Medline Industries, LP, is a licensed Distributor of Dangerous Drug, License No. 01-30000190, which lists James Eveland, as the Responsible Person.

FACTS

1. The Board initiated an investigation of Medline Industries, LP, Distributor of Dangerous Drugs License No. 01-30000190, related to Medline Industries, LP's illegal sales of dangerous drugs to an unlicensed entity.

2. On or about September 28, 2022, the Board sent a Notice of Opportunity for Hearing to Medline Industries, LP, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Medline Industries, LP neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated September 28, 2022; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Medline Industries, LP agrees to pay to the Board a monetary penalty in the amount of $1,125.00. This fine will be attached to your license record and must be paid no later than 180 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. The Board hereby imposes a written reprimand on Medline Industries, LP's WDDD license, number 01-30000190.

5. Medline Industries, LP agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

6. Medline Industries, LP agrees to comply with all federal and state requirements related to Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Medline Industries, LP of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Medline Industries, LP by the Board and will NOT discharge Medline Industries, LP from any obligation under the terms of this Agreement.

7. Medline Industries, LP agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. Medline Industries, LP understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Medline Industries, LP will operate.

10. Medline Industries, LP waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

14. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

15. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

James J. Eveland

James Eveland, on behalf of,
Medline Industries, LP, Respondent

10-25-2022
Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

Shawn C Wilt

Shawn Wilt, RPh, President,
State of Ohio Board of Pharmacy

11.1.2022
Date of Signature

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	12/19/2022	FL	Miami	Miami-Dade

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
A-2022-0333	FL DBPR- Div. of Drugs, Devices, and Cosmetics

Reason/Charge
Customer Licenses, Record Keeping

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
FL DBPR / Medline Industries, LP	Administrative Action

Name of Business/Industry/Entity
Medline Industries, LP

Provide explanation below:

Medline Industries, LP distribution center at 9670 NW 112th Ave, Miami, FL 33178 (FL WDD# #2220297) entered a settlement agreement for alleged violations of selling prescription drugs to an unauthorized recipient and failure to maintain proper records. Medline accepted a physician license for a customer which should have maintained a Healthcare Clinic Establishment Permit. The recordkeeping allegation related to missing NDC numbers on outbound packing slips and invoices.

Corrective Actions:
Medline updated customer licensing requirements for Florida customers and completed an extensive review of all FL customer licenses to verify the correct license type was on file. Medline determined the missing NDC number on the packing slip and invoice occurred due to an internal system error. The error was limited to DSCSA exempt products, i.e. IV fluids. A fix was implemented to correct the issue.

Original Signature (electronic, copies or stamps not accepted)

09/02/2024
Date

FILED
Department of Business and Professional Regulation
Senior Deputy Agency Clerk
CLERK: Brandon Nichols
Date: 12/21/2022
File #: 2022-09829

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner,

v. **Case No.: 2022-031132**

MEDLINE INDUSTRIES, LP,

Respondent,

_____/

FINAL ORDER

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics ("the Department"), in accordance with the provisions of Section 120.57(4), Florida Statutes, hereby enters this Final Order incorporating and adopting, *in toto*, the Settlement Agreement entered into between Medline Industries, LP, and the Department, attached hereto and incorporated by reference.

This Final Order is effective on the date it is filed with the Agency Clerk of the Department as indicated on this Final Order.

DONE and ORDERED this 19th day of December, 2022 in Tallahassee, Florida.

MELANIE S. GRIFFIN, SECRETARY

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

By: _____
Walter S. Copeland, Director
Division of Drugs, Devices, and Cosmetics

Prepared by:

Anthony Coniglio
DDC Chief Attorney

NOTICE OF RIGHT TO APPEAL

Unless expressly waived, any party adversely affected by this Final Order may seek judicial review by filing an original Notice of Appeal with the Clerk of the Department of Business & Professional Regulation, and a copy of the Notice, accompanied by the filing fees prescribed by law, with the clerk of the appropriate District Court of Appeal within 30 days of the effective date of this order, in accordance with Florida Rule of Appellate Procedure 9.110, and Section 120.68, Florida Statutes.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of this Final Order has been provided by regular US mail to: Corporation Service Company, Registered Agent for Medline Industries, LP, 1201 Hays Street, Tallahassee, Florida 32301 on this 21st day of December, 2022.

By: Brandon M. Nichols
Agency Clerk's Office

RECEIVED
[illegible] 09 2022
DRUGS, DEVICES AND COSMETICS

STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION, DIVISION OF DRUGS, DEVICES, AND COSMETICS,

Petitioner, **Case No.: 2022-031132**

v.

MEDLINE INDUSTRIES, LP,

Respondent.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the above-named parties hereby enter into this Settlement Agreement (hereinafter, "this agreement") as disposition of the alleged violations described in the Notice of Violation in case number 2022-031132 (hereinafter, "the allegations"). The terms herein become effective upon rendition of the final order, which shall incorporate this agreement.

The State of Florida, Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (hereinafter, "the Department") is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 20.165 and Chapter 499, Florida Statutes.

STIPULATED FACTS

1. Medline Industries, LP (hereinafter, "Respondent") is permitted by the Department as a prescription drug wholesale distributor, having been issued permit number 22:20297.

2. Respondent's address of record is 9670 Northwest 112th Avenue, Miami, Florida 33178.

3. Respondent was issued a Notice of Violation on October 26, 2022, alleging that it committed certain violations of Chapter 499, Florida Statutes, and the administrative rules adopted

pursuant thereto.

CONCLUSIONS OF LAW

4. Respondent, by and through its undersigned agent, admits that it is subject to the applicable provisions of Chapter 499, Florida Statutes, and the relevant jurisdiction of the Department.

5. Respondent neither admits nor denies the allegations in the Notice of Violation issued in case number 2022-031132, but enters into this agreement for the purpose of resolving the issues raised by the Department.

SETTLEMENT TERMS

6. Respondent affirms that it is currently in compliance with Chapter 499, Florida Statutes.

7. Respondent agrees to pay a settlement amount of six thousand dollars ($6,000.00). **Payment of the settlement amount shall be made only by corporate check, cashier's check, or money order to the Professional Regulation Trust Fund, and shall be remitted to The Florida Department of Business & Professional Regulation, Division of Drugs, Devices and Cosmetics, 2601 Blair Stone Road, Tallahassee, Florida 32399-1047, Attention: Kimberley Johnson, Senior Legal Assistant**. Respondent acknowledges that payment is enclosed with this agreement. The payment and execution of this agreement by Respondent are absolute conditions precedent to the Department's execution of this agreement.

8. The acceptance of this agreement constitutes disciplinary action within the meaning of Section 499.066, Florida Statutes and Rule 61N-1.024, Florida Administrative Code.

STANDARD PROVISIONS

9. It is expressly understood that a violation of the terms of this agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary action may be taken.

10. The parties agree that this agreement will be incorporated into a final order that will be filed with the Department agency clerk and will be a public document. The final order will contain no material terms other than those in this agreement. **The final order shall operate to close case number 2022-031132. The final order shall be the final disposition in this proceeding and shall constitute final agency action with respect thereto.**

11. Respondent expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this agreement and the final order in which this agreement is incorporated, provided the final order does not conflict with this agreement.

12. Each party waives the right to seek any attorney's fees or costs from the other party in connection with this proceeding.

13. This agreement may be executed in any number of counterparts including, without limitation, telecopies and facsimile transmission copies, all of which together shall constitute a single document.

14. The parties agree that this agreement represents a fair, appropriate, and reasonable resolution to, and final disposition of, all disputes and matters made subject hereof.

15. The terms and provisions of this agreement are severable and, if any term or provision is declared or deemed void, invalid, illegal, or otherwise unenforceable, then all remaining terms and provisions shall remain in full force and effect.

16. It is expressly understood that this agreement is subject to approval of the Division of Drugs, Devices, and Cosmetics, and has no force or effect until the Division accepts this

agreement and adopts it in a final order.

17. The signatories hereto are vested with the authority to execute this agreement on behalf of their respective principals and, as duly designated representatives, to fully bind such principals.

MEDLINE INDUSTRIES, LP,

By: _____

Name: Daniel Stevens

Title: Manager Regulatory Affairs

Date: 11/18/2022

FLORIDA DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION DIVISION OF DRUGS, DEVICES, AND COSMETICS,

By: _____

Name: Walter Copeland

Title: Division Director

Date: 12.19.2022

Prepared by:

Anthony Coniglio
DDC Legal Chief
Division of Drugs, Devices, and Cosmetics

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
2601 Blair Stone Road
Tallahassee, Florida 32399
www.MyFloridaLicense.com



Corporation Service Company
Registered Agent for Medline Industries, LP
1201 Hays Street
Tallahassee, Florida 32301

Case No: 2022-031132 (Final Order)

0939

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	07/25/2023	OH/IN	See Below	See Below

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
A-2022-0307; A-2022-0184	Ohio Board of Pharmacy

Reason/Charge
Customer Licenses

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Ohio Board of Pharmacy / Medline Industries, LP	Administrative Action

Name of Business/Industry/Entity
Medline Industries, LP

Provide explanation below:

Medline Industries, LP distribution centers at 1040 Enterprise Parkway South, West Jefferson, OH 43162 (OH License #01-30000190) and 251 Hilton Drive. Jeffersonville, IN 47130 (OH License #01-30000158) entered settlement agreements with the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. The sales occurred between July 2021 and January 2022. Medline maintained valid practitioner licenses on file for each customer instead of the correct d sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file instead of the correct Terminal Distributor Dangerous Drugs license (TDDD). Cases resolved via Settlement Agreement effective 07/19/2023 and 07/25/2023.

Corrective Actions:
Medline updated customer licensing requirements for Ohio customers following OH Case # A-2020-0054. The shipments in this matter occurred between July 2021 and January 2022 while Medline was in the process of reviewing and updating all Ohio customer licenses.

Locations:
1040 Enterprise Parkway South, West Jefferson, OH 43162 (Madison County)
251 Hilton Drive, Jeffersonville, IN 47130 (Clark County)

Original Signature (electronic, copies or stamps not accepted)

09/12/2024
Date

STATE OF OHIO
BOARD OF PHARMACY

July 19, 2023

Medline Industries, LP
c/o James Eveland
1040 Enterprise Parkway South
West Jefferson, OH 43162

Re: Settlement Agreement
License No. 01-30000190

Dear Mercy Primary Care Portage,

Enclosed you will find your Settlement Agreement with the State of Ohio Board of Pharmacy. This document is signed and effective as of July 19, 2023. If you have any questions or concerns, please do not hesitate to contact the Board of Pharmacy and ask to speak with someone in the Legal Department.

Sincerely,

Jennifer Nelson

Jennifer Nelson
Legal Administrative Assistant

Enclosure: July 19, 2023 Settlement Agreement with the State of Ohio Board of Pharmacy

CMRRR: 9414 7118 9956 2233 7395 37

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. A-2022-0307
I-2022-0168

Medline Industries, LP
c/o James Eveland
1040 Enterprise Parkway South
West Jefferson, OH 43162

License No. 01-30000190

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Medline Industries, LP, for the purpose of resolving all issues between the parties relating to the Board investigation of sales of dangerous drugs to unlicensed entities. Together, the Board and Medline Industries, LP are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Medline Industries, LP, is a licensed Distributor of Dangerous Drug, License No. 01-30000190, which lists James Eveland, as the Responsible Person.

FACTS

1. The Board initiated an investigation of Medline Industries, LP, Distributor of Dangerous Drugs License No. 01-30000190, related to Medline Industries, LP's illegal sales of dangerous drugs to an unlicensed entity.

2. On or about 11/16/2022, the Board sent a Notice of Opportunity for Hearing to Medline Industries, LP, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Medline Industries, LP neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated 11/16/2022; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Medline Industries, LP agrees to pay to the Board a monetary penalty in the amount of $875.00.00. This fine will be attached to your license record and must be paid no later than 60 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. The Board hereby imposes a written reprimand on Medline Industries, LP 's WDDD license, number 01-30000190.

5. Medline Industries, LP agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

6. Medline Industries, LP agrees to comply with all federal and state requirements related to Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Medline Industries, LP of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Medline Industries, LP by the Board and will NOT discharge Medline Industries, LP from any obligation under the terms of this Agreement.

7. Medline Industries, LP agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. Medline Industries, LP understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Medline Industries, LP will operate.

10. Medline Industries, LP waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

14. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

15. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

James Eveland, on behalf of, Medline Industries, LP, Respondent	7-11-23 Date of Signature
Attorney for Respondent (if applicable)	Date of Signature
Trina Buettner, RPh, President, State of Ohio Board of Pharmacy	07.19.2023 Date of Signature

STATE OF OHIO
BOARD OF PHARMACY

July 25, 2023

Medline Industries
c/o Filomena Kropiweic
251 Hilton Dr.
Jeffersonville, IN 47130

Re: Settlement Agreement
License No. 0130000158

Dear Medline Industries,

Enclosed you will find your Settlement Agreement with the State of Ohio Board of Pharmacy. This document is signed and effective as of July 25, 2023. If you have any questions or concerns, please do not hesitate to contact the Board of Pharmacy and ask to speak with someone in the Legal Department.

Sincerely,

Jennifer Nelson

Jennifer Nelson
Legal Administrative Assistant

Enclosure: July 25, 2023 Settlement Agreement with the State of Ohio Board of Pharmacy

CMRRR: 9414 7118 9956 2027 4018 31

STATE OF OHIO
BOARD OF PHARMACY

IN THE MATTER OF:

CASE No. A-2022-0184
I-2021-1908

Medline Industries
c/o Filomena Kropiweic
251 Hilton Drive
Jeffersonville, IN 47130

License No. 01-30000158

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Medline Industries, for the purpose of resolving all issues between the parties relating to the Board investigation of illegal sales of dangerous drugs to an unlicensed entity. Together, the Board and Medline Industries are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.56 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.52 of the Ohio Revised Code.

2. Medline Industries is a licensed Distributor of Dangerous Drug, License No. 01-30000158, which lists Filomena Kropiweic as the Responsible Person.

FACTS

1. The Board initiated an investigation of Medline Industries, Distributor of Dangerous Drugs License No. 01-30000158, related to Medline Industries' illegal sales of dangerous drugs to an unlicensed entity.

2. On or about April 25, 2023, the Board sent a Notice of Opportunity for Hearing to Medline Industries, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Medline Industries neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated April 25, 2023; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. Medline Industries agrees to pay to the Board a monetary penalty in the amount of $750.00. This fine will be attached to your license record and must be paid no later than 60 days from the effective date of this Order. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.

4. The Board hereby imposes a written reprimand on Medline Industries' WDDD license, number 01-30000158.

5. Medline Industries agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

6. Medline Industries agrees to comply with all federal and state requirements related to Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Medline Industries of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Medline Industries by the Board and will NOT discharge Medline Industries from any obligation under the terms of this Agreement.

7. Medline Industries agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. Medline Industries understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Medline Industries will operate.

10. Medline Industries waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.

11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

14. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

15. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Filomena Kropiweic — Dec-29-2023

Filomena Kropiweic, on behalf of,
Medline Industries, Respondent

Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

07.25.2023

Trina Buettner, RPh, President,
State of Ohio Board of Pharmacy

Date of Signature

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
	12/21/2023	HI	Kapolei	Honolulu

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
PHA 2023-9-L	Hawaii Department of Commerce and Consumer Affairs

Reason/Charge
Discipline incurred in another jurisdiction

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
HI DCCA / Medline Industries, LP	Administrative Action

Name of Business/Industry/Entity
Medline Industries, LP

Provide explanation below:

Medline Industries, LP distribution center at 2341 Lauwiliwili St, Kapolei, HI 96707 (HI #) entered a Settlement Agreement for discipline incurred in another jurisdiction (OH A-2022-0333, OH A-2022-0307, OH A-2022-0184, and FL 2022-031132)

Original Signature (electronic, copies or stamps not accepted)

07/2/2024
Date

IVY Y. E. KIM 9609
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 S. Beretania Street, 9th Floor
Honolulu, Hawaii 96813
Telephone: (808) 586-2660
E-mail: ikim@dcca.hawaii.gov

Attorney for Department of Commerce
and Consumer Affairs

2023 DEC 15 A 11:07
DEPT. OF COMMERCE AND CONSUMER AFFAIRS
2023 DEC 20 P 12:37
HEARINGS OFFICE

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Wholesale Prescription Drug Distributor License of MEDLINE INDUSTRIES, L.P., Respondent.	PHA 2023-9-L SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" – "3"

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney and Respondent MEDLINE INDUSTRIES, L.P. (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was licensed as a wholesale prescription drug distributor by the Board of Pharmacy (hereinafter the "Board") under the license number PWD-193. The license was issued on or about May 16, 2022. The license will expire or forfeit on or about December 31, 2023, unless timely renewed.

2. Respondent's mailing address for purposes of this action is 2341 Lauwiliwili Street, Kapolei, Hawaii 96707.

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

3. On or about December 19, 2022, the Florida Department of Business & Professional Regulation (hereinafter "Department") issued a Final Order adopting the Settlement Agreement entered into between Respondent and the Department in Case No. 2022-031132 (hereinafter the "Florida Final Order"). The Florida Final Order was based on Respondent's alleged selling of prescription drugs to an unauthorized recipient, failure to maintain records, and failure to provide required documentation to customers. The Florida Final Order is attached hereto as Exhibit "1".

4. On or about July 19, 2023, Respondent and State of Ohio Board of Pharmacy entered into a Settlement Agreement in Case No. A-2022-0307, I-2022-0168, related to Respondent's illegal sales of dangerous drugs to an unlicensed entity. The Settlement Agreement is attached hereto as Exhibit "2".

5. On or about July 25, 2023, Respondent and State of Ohio Board of Pharmacy entered into a Settlement Agreement in Case No. A-2022-0184, I-2021-1908, related to Respondent's illegal sales of dangerous drugs to an unlicensed entity. The Settlement Agreement is attached hereto as Exhibit "3".

6. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes (hereinafter "HRS") § 436B-19(13) (disciplinary action by another state or federal agency).

7. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing, and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent, being at all times relevant herein licensed as a wholesale prescription drug distributor by the Board, acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the license and administrative fines, if the foregoing allegations are proven at hearing. Respondent further understands that RICO enters into this Settlement Agreement and agrees to the specific terms contained in this Settlement Agreement, based upon Respondent's representations made herein.

5. Respondent represents that Exhibits "1" – "3" are true and correct copies of the purported Florida Final Order and Settlement Agreements with the Ohio Board of Pharmacy.

6. Respondent understands that any false or untrue statement or any material misrepresentation or omission of fact by Respondent in this Settlement Agreement may be grounds for further disciplinary action under HRS Chapters 436B and 461.

7. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's license.

8. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

9. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2023-9-L.

10. Respondent understands that this Settlement Agreement may be subject to reporting requirements.

11. Respondent understands this Settlement Agreement is public record pursuant to HRS Chapter 92F.

12. Respondent acknowledges that upon tis approval, this Settlement Agreement constitutes disciplinary action.

C. TERMS OF SETTLEMENT:

1. Administrative Fine. Respondent agrees to pay an administrative fine in the amount of TWO THOUSAND TWO HUNDRED FIFTY AND NO/100 DOLLARS ($2,250.00). Payment shall be made by **cashier's check or money order made payable to "DCCA – Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn.: Ivy Y. E. Kim, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph C.1. above, Respondent's license shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of licensure to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new license until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become licensed again, Respondent must apply to the Board for a new license pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible Further Sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board

may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of pharmacies in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5., C.6., and C.7. below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent, nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion, or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion, or promise made by RICO or any of its agents, employees, representatives, or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

[Remainder of this page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below. Each signatory to this Settlement Agreement hereby represents and warrants that he/she is authorized to execute and deliver this Settlement Agreement in the capacity shown below.

DATED: Northfield (City), IL (State), 09/07/2023 (Date).

MEDLINE INDUSTRIES, L.P.
Respondent

By: _____ (Signature)

Daniel Stevens (Print Name)

Its Manager Regulatory Affairs (Print Title)

DATED: Honolulu, Hawaii, 10/11/2023.

_____

IVY Y. E. KIM
Attorney for Department of Commerce
and Consumer Affairs

IN THE MATTER OF THE WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR LICENSE OF MEDLINE INDUSTRIES, L.P.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBITS "1" – "3"; RICO CASE NO. PHA 2023-9-L.

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

ALANNA ISOBE Chair	December 21, 2023 **DATE**
PATRICK ADAMS Vice Chair	**MARK BROWN**
CATALINA CROSS	Kent Kikuchi **KENT KIKUCHI**
BRANDON RABANG	**SHERI TOKUMARU**

PVL 11/09/22

POWER OF ATTORNEY

MEDLINE INDUSTRIES, LP, an Illinois limited partnership, having a principal place of business at 3 Lakes Drive, Northfield, Illinois, 60093 (the "Company"), herewith authorize and entrust a Power of Attorney to DANIEL A. STEVENS, United States citizen, Manager Regulatory Affairs, with permanent residence at 4217 Arlington Avenue, Sacramento, CA 95820 with full signatory rights on behalf of the Company as follows:

To be our true and lawful Agent with as full as legally necessary powers to submit, execute and prosecute applications in the name of the Company, for permits, registrations and other governmental authorizations, relating in any way to the quality assurance, quality control, regulatory, warehousing and sterilizing functions of the Company, and to represent the Company and take all necessary actions in legal matters and all other matters towards all third parties and all public authorities, federal, state or municipal, and towards all other divisions, subdivisions, departments, units or all secretariats of the above, relating in any way to the quality assurance, quality control, regulatory, warehousing and sterilizing functions of the Company.

This power of Attorney is valid until revoked in writing by the Company.

Dated: October 11, 2022

Medline Industries, LP

By: Mozart GP, LLC
Its: General Partner

By: _____
Name: Alexander M. Liberman
Title: Assistant Secretary

ACKNOWLEDGEMENT

STATE OF ILLINOIS
COUNTY OF COOK

This instrument was acknowledged before me on October 11, 2022 by Alexander M. Liberman, as Assistant Secretary of Mozart GP, LLC, as General Partner of Medline Industries, LP.

Barbara Bychowski
(Signature of Notary Public)

(Seal)

"OFFICIAL SEAL"
BARBARA BYCHOWSKI
NOTARY PUBLIC, STATE OF ILLINOIS
MY COMMISSION EXPIRES 8/29/2026

41

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10)

Section 1: General Information

Facility Name: Optum Specialty Services, LLC

Physical Address: 8950 Global Way SW, Suite 100

City: Etna State: OH Zip: 43062

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

City: _____ State: _____ Zip: _____

Telephone: (380) 218-3900 Website: https://business.optum.com/en/specialty-distribution

Name of Designated Representative (DR): Andrew Wayt

Licensing Company Email: OSSLicensing@optum.com DR Email: andrew_wayt@optum.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies ☐ Practitioners ■ Hospitals ■ Wholesalers ☐ Veterinarians ☐ Others:	■ Dangerous Drugs ☐ Controlled Substances ☐ [a]Medical Products (medical devices, equipment, supplies, gases) ☐ Others:	☐ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ■ Others: Third-Party Logistics (3PL)

N/A

Section 2: ONLY COMPLETE THIS SECTION IF THE COMPANY IS WHOLESALING [a]Medical Products (medical devices, equipment, supplies and gases). Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 3 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 4: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Optum Specialty Distribution, LLC
Address: 8940 Global Way SW City: Etna State: OH Zip: 43062
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): N/A
Corporation Name: UnitedHealth Group Incorporated
Mailing Address: 1 Health Drive
City: Eden Prairie State: MN Zip: 55344
Telephone: 952-936-1300 Email: kelly.orourke@uhg.com
Contact Person Name: Kelly O'Rourke

Date of SEC Registration: 10/17/1984 | SEC Registration Number: CIK 0000731766 | Stock Exchange Symbol: UNH

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 8: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 9: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 10: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale [a]Medical Products (medical devices, equipment, supplies, gases). (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Products (medical devices, equipment, supplies, gases), supply a copy of proof of insurance (NAC 639.6957).** The Medical Products wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 9)				
• **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20NRS%20639.500%20-%20Effective%2001.07.2026%20-%20Wholesaler%20-%20Post%20on%201.26.26.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Optum Specialty Services, LLC

Facility Name

Karen Bohmer

Print Name of Authorized Person Submitting Application

Karen Bohmer

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

8/18/26

Date

Board Use Only	Date Received: 8/20/26	Amount: $1000 CK 1716062417

Optum

August 12, 2026

To: Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, # 206
Reno, NV 89521

Re: Optum Specialty Services, LLC
8950 Global Way SW, Suite 100
Etna OH 43062

Please accept this letter as formal notice that Andrew Wayt, in his capacity as Designated Representative of the above-mentioned Third-Party Logistics Provider, is an authorized person to speak on behalf of Optum Specialty Services, LLC regarding the application as well as any Nevada Board of Pharmacy Board Meetings.

If you should have any questions or concerns, or require additional information, please contact Tara Mihans, Wholesale & 3PL Licensing Manager via telephone at 612-474-7302 or email Tara.Mihans@optum.com.

Thank you,

Karen Bohmer

Karen Bohmer, Secretary
Optum Specialty Services, LLC

NABP ACCREDITED

DRUG DISTRIBUTOR

Optum Specialty Services, LLC

located at

8950 Global Way SW, Ste 100 Etna, OH 43062

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.



Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

0967

Optum

Officer List

Entity			
Optum Specialty Services, LLC 8950 Global Way SW Suite 100 Etna OH 43062 Tax ID: 92-2947779			
Officers of Entity	**Title**	**% of Ownership**	**Business Address**
Christopher J. Stidman	Manager, CEO & President	0%	1 Optum Circle, Suite 100 Eden Prairie MN 55344
Marilyn V. Hirsch	Treasurer	0%	1 Optum Circle, Suite 100 Eden Prairie MN 55344
Karen E. Bohmer	Secretary	0%	1 Optum Circle, Suite 100 Eden Prairie MN 55344

Optum

Optum Specialty Services, LLC

Organizational Chart

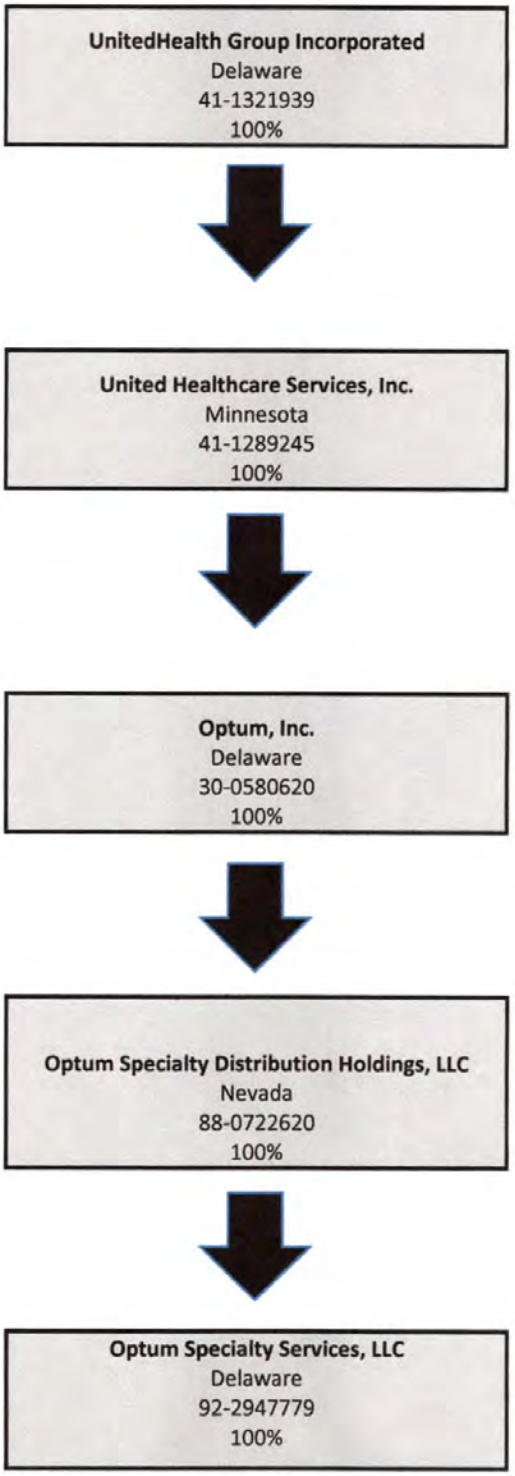


Exhibit 21.1

Significant Subsidiaries of the Company

Listed below are the significant subsidiaries (as defined in Rule 1-02(w) of Regulation S-X) of UnitedHealth Group Incorporated as of December 31, 2025. This list does not include Company subsidiaries that did not meet the conditions required to be deemed a significant subsidiary as of December 31, 2025.

Name of Entity	State of Jurisdiction or Domicile	Doing Business As
Collaborative Care Holdings, LLC	Delaware	
Optum, Inc.	Delaware	
OptumHealth Holdings, LLC	Delaware	
OptumRx Administrative Services, LLC	Texas	Alaska Business License #2143946
OptumRx Group Holdings, Inc.	Delaware	
OptumRx Holdings I, LLC	Delaware	
UHIC Holdings, Inc.	Delaware	OneNet PPO
United HealthCare Services, Inc.	Minnesota	AmeriChoice EverCare Health Professionals Review Healthmarc HealthPro Institute for Human Resources UHC Management Company UHC Management Company, Inc. United Health Care United HealthCare United HealthCare Corporation United HealthCare Management Company, Inc. United HealthCare Management Services United HealthCare Services of Minnesota United HealthCare Services of Minnesota, Inc. United Resource Networks United Resource Networks, Inc. UnitedHealthcare UnitedHealthcare Medicare Customer Service Center UnitedHealthcare MedicareStore
UnitedHealthcare Insurance Company	Connecticut	UnitedHealthcare Community Plan
UnitedHealthcare, Inc.	Delaware	

Exhibit 21.1

Subsidiaries of the Company

Listed below are subsidiaries of UnitedHealth Group Incorporated as of December 31, 2024. Those subsidiaries not listed would not, in the aggregate, constitute a "significant subsidiary" of UnitedHealth Group Incorporated, as that term is defined in Rule 1-02(w) of Regulation S-X.

Optum Services (Puerto Rico) LLC	Puerto Rico	
Optum Services, Inc.	Delaware	Alaska Business License 2186405
Optum Solutions UK Holdings Limited	United Kingdom	
Optum Specialty Distribution Holdings, LLC	Nevada	
Optum Specialty Distribution, LLC	Delaware	Alaska Business License
Optum Specialty Services, LLC	Delaware	

Optum

List top four corporation shareholders and their percent ownership

- List the top four corporation shareholders and their percent ownership.

Below are the Top 4 Shareholders for UnitedHealth Group Incorporated as of its most recent SEC filings.

1. **BlackRock Inc.** - ~8.5%
2. **Vanguard Capital Management LLC** ~ 6.5%
3. **State Street Corp.** – ~ 5.0%
4. **Capital World Investors** – ~ 3.5%

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "OPTUM SPECIALTY SERVICES, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF AUGUST, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "OPTUM SPECIALTY SERVICES, LLC" WAS FORMED ON THE FIFTEENTH DAY OF AUGUST, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

7624154 8300

SR# 20264030268

Authentication: 204792638

Date: 08-11-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF THE SECRETARY OF STATE

I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show OPTUM SPECIALTY SERVICES, LLC, a Delaware Limited Liability Company, Registration Number 5097857, was registered in the State of Ohio on August 18, 2023, is currently authorized to transact business in this state.

Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 3rd day of April, A.D. 2026.

Ohio Secretary of State

Validation Number: 202609303580

Ohio Board of Pharmacy

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until June 30, 2027.

Optum Specialty Services, LLC

8950 Global Way SW Ste 100

Etna, OH 43062

License Number: 0170000130

License Type: Third-Party Logistics - Category 2

Sub-Category: 3PL – Third-Party Logistics

Expiration Date: June 30, 2027

Responsible Person – Print, sign, and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
Andrew Wayt	Andrew Wayt

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request in eLicense Ohio - elicense.ohio.gov.

Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

Board of Pharmacy

VERIFICATION OF LICENSURE

BUSINESS NAME:	Optum Specialty Services, LLC
LOCATION:	8950 Global Way SW Ste 100 Etna, OH 43062
LICENSE NUMBER:	0170000130
TYPE OF LICENSE:	Third-Party Logistics - Category 2
ORIGINAL LICENSURE DATE:	February 24, 2024
EXPIRATION DATE:	June 30, 2027
CURRENT LICENSE STATUS:	Active
CURRENT LICENSE SUB STATUS:	N/A
BOARD ACTION:	No (If Board Action is "Yes", you may find more information at elicense.ohio.gov)
DATE OF VERIFICATION:	8/7/2026

Grant Miller
Licensing Administrator
Ohio Board of Pharmacy

Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

Optum

List containing each employee, agent, personal representative, lender or holder of indebtedness of the applicant

- **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**

Please see applicable portion Optum Specialty Services, LLC

Optum Specialty Services, LLC 's Current Employees

Brian McMahon – Site Director, Operations
Brian_McMahon@optum.com

Andrew Wayt – Manager, Operations, Designated Representative
Andrew_Wayt@optum.com

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 1-10864

UNITEDHEALTH GROUP

UnitedHealth Group Incorporated

(Exact name of registrant as specified in its charter)

Delaware	**41-1321939**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1 Health Drive			**655 New York Avenue NW**		
Eden Prairie,	**Minnesota**	**55344**	**Washington,**	**DC**	**20001**
(Address of principal executive offices)		**(Zip Code)**	**(Address of principal executive offices)**		**(Zip Code)**

(800) 328-5979

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $.01 par value	**UNH**	**New York Stock Exchange**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Non-accelerated filer	☐
Smaller reporting company	☐			Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of voting stock held by non-affiliates of the registrant as of June 30, 2025 was $281,907,836,350 (based on the last reported sale price of $311.97 per share on June 30, 2025 as reported on the New York Stock Exchange), excluding only shares of voting stock held beneficially by directors, executive officers and subsidiaries of the registrant.

As of February 20, 2026, there were 907,675,839 shares of the registrant's Common Stock, $.01 par value per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this report, to the extent not set forth herein, is incorporated by reference from the registrant's definitive proxy statement relating to its 2026 Annual Meeting of Shareholders. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

UNITEDHEALTH GROUP

Table of Contents

		Page
	Part I	
Item 1.	Business	1
Item 1A.	Risk Factors	10
Item 1B.	Unresolved Staff Comments	21
Item 1C.	Cybersecurity	21
Item 2.	Properties	22
Item 3.	Legal Proceedings	22
Item 4.	Mine Safety Disclosures	22
	Part II	
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	23
Item 6.	Reserved	24
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	25
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	37
Item 8.	Financial Statements and Supplementary Data	38
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	72
Item 9A.	Controls and Procedures	72
Item 9B.	Other Information	74
Item 9C.	Disclosure Regarding Foreign Jurisdictions That Prevent Inspections	74
	Part III	
Item 10.	Directors, Executive Officers and Corporate Governance	74
Item 11.	Executive Compensation	75
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	75
Item 13.	Certain Relationships and Related Transactions, and Director Independence	75
Item 14.	Principal Accountant Fees and Services	75
	Part IV	
Item 15.	Exhibit and Financial Statement Schedules	76
Item 16.	Form 10-K Summary	83
Signatures		84

PART I

ITEM 1. BUSINESS

OUR BUSINESSES

Overview

The terms "we," "our," "us," "its," "UnitedHealth Group," or the "Company" used in this report refer to UnitedHealth Group Incorporated and its subsidiaries.

UnitedHealth Group Incorporated is a health care and well-being company with a mission to help people live healthier lives and help make the health system work better for everyone. Our two distinct, yet complementary businesses — Optum and UnitedHealthcare — are working to help build a modern, high-performing health system through improved access, affordability, outcomes and experiences for the individuals and organizations we are privileged to serve.

The ability to analyze complex data and apply deep health care expertise and insights allows us to serve patients, consumers, care providers, businesses, communities and governments with more innovative products and complete, end-to-end offerings for many of the biggest challenges facing health care today.

Optum seeks to create a higher-performing, value-oriented and more connected approach to health care. Bringing together clinical expertise, technology and data to make care simpler, more effective and more affordable, we seek to advance whole-person health, creating a seamless consumer experience and supporting clinicians with insights to deliver personalized, evidence-based care. Optum serves the broad health care marketplace, including patients and consumers, payers, care providers, employers, governments and life sciences companies, through its Optum Health, Optum Insight and Optum Rx businesses. These businesses improve overall health system performance by optimizing health care quality and delivery, reducing costs and improving patient, consumer and provider experience, leveraging distinctive capabilities in data and analytics, pharmacy care services, health care operations, population health and health financial services.

UnitedHealthcare offers a full range of health benefits, designed to simplify the health care experience and make it more affordable for consumers to access high-quality care. UnitedHealthcare Employer & Individual serves consumers and employers, ranging from individuals and sole proprietorships to large, multi-site and national employers and public sector employers. UnitedHealthcare Medicare & Retirement delivers health and well-being benefits to seniors and other Medicare eligible consumers. UnitedHealthcare Community & State serves consumers who are economically disadvantaged, the medically underserved and those without the benefit of employer sponsored health benefits coverage.

We have four reportable segments:

- Optum Health;
- Optum Insight;
- Optum Rx; and
- UnitedHealthcare, which includes UnitedHealthcare Employer & Individual, UnitedHealthcare Medicare & Retirement and UnitedHealthcare Community & State.

2026 Business Realignment

On January 1, 2026, we realigned certain of our businesses to respond to changes in the markets we serve and the opportunities that are emerging as the health system evolves. Optum Financial, including Optum Bank, which was historically included in Optum Health, will now be included in Optum Insight. Our reportable segments will remain unchanged, with prior period segment financial information being recast to conform to the 2026 presentation, beginning with our Quarterly Report on Form 10-Q for the three months ended March 31, 2026 filed with the Securities and Exchange Commission (SEC).

Optum

Optum is an information and technology-enabled health services business serving the broad health care marketplace, including:

- Those who need care: patients who need the right care, information, resources, products and engagement to improve their health, achieve their health goals and receive an improved patient experience that is personalized, comprehensive and delivered in all care settings, including in-home and virtually.
- Those who provide care: physicians, hospitals, pharmacies and others seeking to improve the health system and reduce the administrative burden, allowing for providers to focus time on patients leading to the best possible patient care and experiences while achieving better health outcomes at lower costs. Improved health outcomes are achieved by utilizing our clinical expertise, data and analytics to better understand, treat and prevent consumers' health conditions and ensure they receive the best evidence-based care.
- Those who pay for care: consumers; employers; health plans; and state, federal and municipal agencies devoted to ensuring the people they sponsor receive high-quality care, administered and delivered efficiently and effectively, all while driving health equity so that every individual, family and community has access to the care they need.
- Those who innovate for care: global life sciences organizations dedicated to developing more effective approaches to care, enabling technologies and medicines to improve care delivery and health outcomes.

Optum operates three business segments which combine distinctive capabilities in value-based care, population health, health care operations, data and analytics and pharmacy care services:

- Optum Health delivers patient-centered care, care management, wellness and consumer engagement, and health financial services;
- Optum Insight offers data, analytics, research, consulting, technology and managed services solutions; and
- Optum Rx provides diversified pharmacy care services.

Optum Health

Optum Health provides comprehensive and patient-centered care, addressing the physical, mental, social, and financial well-being of 95 million consumers and serves more than 100 health payer partners. We engage people in the most appropriate care settings, including clinical sites, in-home and virtual. Optum Health delivers primary, specialty and surgical care; helps patients and providers navigate and address complex, chronic and behavioral health needs; offers post-acute care planning services; and serves consumers and care providers through advanced, on-demand digital health technologies, such as telehealth and remote patient monitoring, and innovative health care financial services. Optum Health works directly with patients, consumers, care delivery systems, providers, employers, payers, and public-sector entities to provide high quality, accessible and equitable care with improved health outcomes and reduced total cost of care. Optum Health enables care providers to transition from traditional fee-for-service payment models to performance-based delivery and payment models designed to improve patient health outcomes and experience through value-based care.

Optum Health offerings include fully accountable value-based arrangements, where Optum Health assumes responsibility for health care costs in exchange for a monthly premium. Offerings also include administrative fee arrangements, where Optum Health manages or administers products and services in exchange for a monthly fee, and fee-for-service arrangements, where Optum Health delivers health-related products and medical services for patients at a contracted fee.

Optum Financial, including Optum Bank, serves consumers through nearly 26 million consumer accounts with more than $27 billion in assets under management as of December 31, 2025. Organizations across the health system rely on Optum Financial to manage and improve payment flows through its highly automated, scalable, end-to-end digital payment and financing systems and integrated card solutions. For financial services offerings, Optum Financial charges fees and earns investment and interest income on managed funds and loans.

Optum Health sells its products primarily through its direct sales force, strategic collaborations and external producers in three key areas: employers, including large, mid-sized and small employers; payers including health plans, third-party administrators (TPAs), underwriter/stop-loss carriers and individual product intermediaries; and public entities, including the U.S. Departments of Health and Human Services (HHS), Veterans Affairs, Defense, and other federal, state and local health care agencies.

Optum Insight

Optum Insight connects the health care system with services, analytics and platforms that make clinical, administrative and financial processes simpler and more efficient for all participants in the health care system. Hospital systems, physicians, health plans, public entities, life sciences companies and other organizations comprising the health care industry depend on Optum Insight to help them improve performance and reduce costs through administrative efficiency and payment simplification, advance care quality through evidence-based standards built directly into clinical workflows, meet compliance mandates and modernize their core operating systems to meet the changing needs of the health system.

Health Systems. Serves hospitals, physicians and other care providers to improve operating performance, better coordinate care and reduce administrative costs through technology and services to improve population health management, patient engagement, revenue cycle management and strategic growth plans.

Health Plans. Serves health plans by improving financial performance and enhancing outcomes through proactive analytics, a comprehensive payment integrity portfolio and technology-enabled and staff-supported risk and quality services. Optum Insight helps health plans navigate a dynamic environment defined by shifts in employer vs. public-sector coverage, the demand for affordable benefit plans and the need to leverage new technology to reduce complexity.

State Governments. Provides advanced technology and analytics services to modernize the administration of critical safety net programs, such as Medicaid, while improving cost predictability.

Life Sciences Companies. Combines data and analytics expertise with comprehensive technologies and health care knowledge to help life sciences companies, including those in pharmaceuticals and medical technology, adopt a more comprehensive approach to advancing therapeutic discoveries and improving clinical outcomes.

Many of Optum Insight's software and information products and professional services are delivered over extended periods, often several years. Optum Insight maintains an order backlog to track unearned revenues under these long-term arrangements. The backlog consists of estimated revenue from signed contracts, other legally binding agreements and anticipated contract renewals based on historical experience with Optum Insight's customers. Optum Insight's aggregate backlog as of December 31, 2025 was approximately $31.1 billion, of which $18.3 billion is expected to be realized within the next 12 months. The aggregate backlog includes $12.9 billion related to affiliated agreements. Optum Insight's aggregate backlog as of December 31, 2024, was $32.8 billion, including $12.5 billion related to affiliated agreements.

Optum Insight's products and services are sold primarily through a direct sales force. Optum Insight's products are also supported and distributed through an array of alliances and business partnerships with other technology vendors, who integrate and interface Optum Insight's products with their applications.

Optum Rx

Optum Rx provides a full spectrum of pharmacy care services through its network of approximately 64,000 retail pharmacies, through home delivery, specialty and community health pharmacies, the provision of in-home and community-based infusion services and through rare disease and gene therapy support services. It also offers direct-to-consumer solutions.

Optum Rx manages a broad range of prescription drug spend, including widely available retail drugs as well as limited and ultra-limited distribution drugs in oncology, human immunodeficiency virus, pain management and ophthalmology. Optum Rx serves the growing pharmacy needs of people with behavioral health and substance use disorders. In 2025, Optum Rx managed $188 billion in pharmaceutical spending, including nearly $87 billion in specialty pharmaceutical spending.

Optum Rx serves health benefits providers, large national employer plans, unions and trusts, purchasing coalitions and public-sector entities. Optum Rx sells its services through direct sales, health insurance brokers and other health care consultants.

Optum Rx offers multiple clinical programs, digital tools and services to help clients manage overall pharmacy and health care costs in a clinically appropriate manner which are designed to deliver improved consumer experiences, better health outcomes and a lower total cost of care. Optum Rx provides various utilization management, medication management, quality assurance, adherence and counseling programs to complement each client's plan design and clinical strategies. Optum Rx is accelerating the integration of medical, pharmacy and behavioral care and treating the whole patient by embedding our pharmacists as key members of the patient care team.

UnitedHealthcare

Through its health benefits offerings, UnitedHealthcare is enabling better health, creating a better health care experience for its customers and helping to control rising health care costs. UnitedHealthcare's market position is built on:

- strong local-market relationships;
- the breadth of product offerings, based upon extensive expertise in distinct market segments in health care;
- service and advanced technology, including digital consumer engagement;
- competitive medical and operating cost positions;
- effective clinical engagement; and
- innovation for customers and consumers.

UnitedHealthcare arranges for discounted access to care through its extensive networks and uses Optum's capabilities to help coordinate and provide patient care, improve affordability of medical care, analyze cost trends, manage pharmacy care services, work with care providers more effectively and create a simpler and more satisfying consumer and physician experience.

UnitedHealthcare is subject to extensive government regulation. See further discussion of our regulatory environment below under "Government Regulation" and in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

UnitedHealthcare Employer & Individual

Domestically, UnitedHealthcare Employer & Individual offers a comprehensive array of consumer-oriented health benefit plans and services for large national employers, public sector employers, mid-sized employers, small businesses, and individuals. As of December 31, 2025, UnitedHealthcare Employer & Individual provides access to medical services for 29.7 million people.

UnitedHealthcare Employer & Individual offers risk-based products under which it assumes responsibility for medical and administrative costs in exchange for a monthly premium, typically a fixed rate per individual served for a one-year period. For customers that elect to self-fund the health care costs and retain the financial risk of medical benefits for their employees and dependents, UnitedHealthcare Employer & Individual provides administrative and management services. These services include coordination of medical and related services, transaction processing and access to a contracted network of physicians, hospitals and other health care providers, including providers of dental and vision services. The business focuses on delivering customized benefit solutions and clinical programs designed to help employers and individuals manage costs while maintaining quality coverage and supporting health and well-being, with the shared goal of improving outcomes for patients and the health system.

UnitedHealthcare Employer & Individual distributes its products through a variety of channels, depending on the specific product. These channels include consultants or direct sales, brokers and agents, wholesale agents or agencies that contract with health insurance carriers to distribute individual or group benefits, professional employer organizations and associations, and both multi-carrier and proprietary private exchange marketplaces.

UnitedHealthcare Employer & Individual provides employer-sponsored health benefits, as well as individual and family plans through portfolio of products which include consumer engagement products, such as high-deductible consumer driven benefit plans and a variety of innovative consumer centric products; traditional products; clinical and pharmacy products; and specialty benefits, such as vision, dental, accident protection, critical illness, disability and hospital indemnity offerings.

UnitedHealthcare Medicare & Retirement

UnitedHealthcare Medicare & Retirement provides health and well-being services to seniors and other Medicare eligible consumers, addressing their unique needs. UnitedHealthcare Medicare & Retirement has distinct benefit designs, pricing, underwriting, clinical program management and marketing capabilities dedicated to health products and services in this market.

UnitedHealthcare Medicare & Retirement offers a selection of products allowing people choice in obtaining the health coverage and services they need as their circumstances change. These offerings include care management and health system navigator services, clinical management programs, nurse health line services, 24-hour access to health care information, access to discounted health services from a network of care providers and administrative services.

UnitedHealthcare Medicare & Retirement has extensive distribution capabilities and experience, including direct marketing to consumers on behalf of its key clients, a membership organization, and state and U.S. government agencies. Products are also offered through agents, employer groups and digital channels.

Major product categories include:

Medicare Advantage. Provides health care coverage for seniors and other eligible Medicare beneficiaries through the Medicare Advantage program administered by the Centers for Medicare & Medicaid Services (CMS), including Medicare Advantage HMO plans, Preferred Provider Organization (PPO) plans, Point-of-Service plans, Private-Fee-for-Service plans and Special Needs Plans (SNPs). Under the Medicare Advantage program, UnitedHealthcare Medicare & Retirement provides health benefits coverage in exchange for a fixed monthly premium per member from CMS plus, in some cases, monthly consumer premiums. Premium amounts received from CMS vary based on the geographic areas in which individuals reside; demographic factors such as age, gender and institutionalized status; and the health status of the individual. UnitedHealthcare Medicare & Retirement served 8.4 million people through its Medicare Advantage products as of December 31, 2025.

We have continued to enhance our offerings, focusing on more digital and physical care resources in the home, expanding our concierge navigation services and enabling the home as a safe and effective setting for care. For example, through our HouseCalls program, nurse practitioners performed 3.1 million clinical preventive home care visits in 2025 to address unmet care opportunities and close gaps in care.

Medicare Part D. Provides Medicare Part D benefits to beneficiaries through its Medicare Advantage and stand-alone Medicare Part D plans. The stand-alone Medicare Part D plans address a large spectrum of people's needs and preferences for their prescription drug coverage, including low-cost prescription options. As of December 31, 2025, UnitedHealthcare enrolled 10.4 million people in the Medicare Part D programs, including 2.8 million individuals in stand-alone Medicare Part D plans, with the remainder in Medicare Advantage plans incorporating Medicare Part D coverage.

Medicare Supplement. Provides a full range of supplemental products at diverse price points. These products cover various levels of coinsurance and deductible gaps to which seniors are exposed in the traditional Medicare program. UnitedHealthcare Medicare & Retirement served 4.3 million seniors nationwide through various Medicare Supplement products as of December 31, 2025.

Premium revenues from CMS represented 44% of UnitedHealth Group's total consolidated revenues for the year ended December 31, 2025, most of which were generated by UnitedHealthcare Medicare & Retirement.

UnitedHealthcare Community & State

UnitedHealthcare Community & State is dedicated to serving state programs caring for the economically disadvantaged, the medically underserved and those without the benefit of employer-funded health care coverage, typically in exchange for a monthly premium per member from the state program. UnitedHealthcare Community & State's primary customers oversee Medicaid plans, including Temporary Assistance to Needy Families; Children's Health Insurance Programs (CHIP); Dual SNPs (DSNPs); Long-Term Services and Supports (LTSS); Aged, Blind and Disabled; and other federal, state and community health care programs. As of December 31, 2025, UnitedHealthcare Community & State participated in programs in 32 states and the District of Columbia, and served nearly 7.4 million people; including 1.2 million people through Medicaid expansion programs in 19 states under the Patient Protection and Affordable Care Act (ACA).

States using managed care services for Medicaid beneficiaries select health plans by using a formal bid process or by awarding individual contracts. These health plans and care programs are designed to address the complex needs of the populations they serve, including the chronically ill, people with disabilities and people with a higher risk of medical, behavioral and social conditions. UnitedHealthcare Community & State administers benefits for the unique needs of children, pregnant women, adults, seniors and those who are institutionalized or are nursing home eligible. These individuals often live in medically underserved areas and are less likely to have a consistent relationship with the medical community or a care provider. They also often face significant social and economic challenges.

GOVERNMENT REGULATION

Our businesses are subject to comprehensive U.S. federal and state and international laws and regulations. We are regulated by government agencies, which generally have discretion to issue regulations and interpret and enforce laws and regulations. U.S. federal and state and international governments continue to consider and enact various legislative and regulatory proposals which could materially impact certain aspects of the health care system and our operations. New laws and regulations, or changes in the interpretation of existing laws and regulations, including as a result of changes in the political environment, could adversely affect our businesses.

See Part I, Item 1A, "Risk Factors" for a discussion of the risks related to our compliance with U.S. federal and state and international laws and regulations.

U.S. Federal Laws and Regulation

When we contract with the federal government, we are subject to federal laws and regulations relating to the award, administration and performance of U.S. government contracts. CMS regulates our UnitedHealthcare businesses and certain aspects of our Optum businesses. Payments by CMS to our businesses are subject to regulations, including those governing fee-for-service and the submission of information relating to the health status of enrollees for purposes of determining the amounts of certain payments to us. CMS also has the right to audit our performance to determine our compliance with CMS contracts and regulations and the quality of care we provide to Medicare beneficiaries. Our commercial business is further subject to CMS audits related to medical loss ratios (MLRs) and risk adjustment data.

UnitedHealthcare Community & State has Medicaid and CHIP contracts, which are subject to federal regulations regarding services to be provided to Medicaid enrollees, payment for those services and other aspects of these programs. There are many regulations affecting Medicare and Medicaid compliance, and the regulatory environment with respect to these programs is complex.

Our businesses are also subject to laws and regulations relating to consumer protection, anti-fraud and abuse, anti-kickbacks, false claims, prohibited referrals, inappropriate reduction or limitation of health care services, anti-money laundering and securities and antitrust compliance.

Privacy, Security and Data Standards Regulation. Certain of our operations are subject to regulation under the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA), which apply to both the group and individual health insurance markets, including self-funded employee benefit plans. Federal regulations related to HIPAA contain minimum standards for electronic transactions and code sets and for the privacy and security of protected health information.

Our businesses must comply with the Health Information Technology for Economic and Clinical Health Act (HITECH), which regulates matters relating to privacy, security and data standards. HITECH imposes requirements on uses and disclosures of health information; includes contracting requirements for HIPAA business associate agreements; extends parts of HIPAA privacy and security provisions to business associates; adds federal data breach notification requirements for covered entities and business associates and reporting requirements to HHS and the Federal Trade Commission (FTC) and, in some cases, to the local media; strengthens enforcement and imposes higher financial penalties for HIPAA violations and, in certain cases, imposes criminal penalties for individuals, including employees. In the conduct of our business, depending on the circumstances, we may act as either a covered entity or a business associate.

The use and disclosure of individually identifiable health data by our businesses are also regulated in some instances by other federal laws, including the Gramm-Leach-Bliley Act (GLBA) or state statutes implementing GLBA. These federal laws and state statutes generally require insurers to provide customers with notice regarding how their non-public personal health and financial information is used and the opportunity to "opt out" of certain disclosures before the insurer shares such information with a third party, and generally prescribe safeguards for the protection of personal information. Neither the GLBA nor HIPAA privacy regulations preempt more stringent state laws and regulations, which may apply to us, as discussed below. Federal consumer protection laws may also apply in some instances to privacy and security practices related to personally identifiable information.

ERISA. The Employee Retirement Income Security Act of 1974, as amended (ERISA), regulates how our services are provided to or through certain types of employer-sponsored health benefit plans. ERISA is a set of laws and regulations subject to interpretation by the U.S. Department of Labor (DOL) as well as the federal courts. ERISA sets forth standards on how our business units may do business with employers who sponsor employee health benefit plans, particularly those that maintain self-funded plans. Regulations established by the DOL subject us to additional requirements for administration of benefits, claims payment and member appeals under health care plans governed by ERISA.

State Laws and Regulation

Health Care Regulation. Our insurance and HMO subsidiaries must be licensed by the jurisdictions in which they conduct business. All of the states in which our subsidiaries offer insurance and HMO products regulate those products and operations. The states require periodic financial reports and establish minimum capital or restricted cash reserve requirements. The National Association of Insurance Commissioners (NAIC) has adopted model regulations which require expanded governance practices and risk and solvency assessment reporting. Most states have adopted these or similar measures to expand the scope of regulations relating to corporate governance and internal control activities of HMOs and insurance companies. We are required to maintain a risk management framework and file a confidential self-assessment report with state insurance regulators. We file reports annually with Connecticut, our lead regulator, and with New York, as required by the state's regulation.

Our health plans and insurance companies are regulated under state insurance holding company regulations. Such regulations generally require registration with applicable state departments of insurance and the filing of reports describing capital structure, ownership, financial condition, certain affiliated transactions and general business operations. Most state insurance

holding company laws and regulations require prior regulatory approval of acquisitions and material affiliated transfers of assets, as well as transactions between the regulated companies and their parent holding companies or affiliates. These laws and regulations may restrict the ability of our regulated subsidiaries to pay dividends to our holding companies.

Some of our business activity is subject to other health care-related regulations and requirements, including PPO, Managed Care Organization (MCO), utilization review (UR), behavioral health, TPA, pharmacy care services, durable medical equipment or care provider-related regulations and licensure requirements. These regulations differ from state to state and may contain network, contracting, product and rate, licensing and financial and reporting requirements. Health care-related laws and regulations set specific standards for delivery of services, mental health parity, appeals, grievances and payment of claims, adequacy of health care professional networks, fraud prevention, protection of consumer health information, pricing and underwriting practices and covered benefits and services. State health care anti-fraud and abuse prohibitions encompass a wide range of activities, including kickbacks for referral of members, billing for unnecessary medical services and improper marketing. Certain of our businesses are subject to state general agent, broker and sales distribution laws and regulations. UnitedHealthcare Community & State and certain of our Optum businesses are subject to regulation by state Medicaid agencies which oversee the provision of benefits to our Medicaid and CHIP beneficiaries and to our beneficiaries dually eligible for Medicare and Medicaid. We also contract with state governmental entities and are subject to state laws and regulations relating to the award, administration and performance of state government contracts.

State Privacy and Security Regulations. A number of states have adopted laws and regulations which may affect our privacy and security practices, such as state laws governing the use, disclosure and protection of social security numbers and protected health information or which are designed to implement GLBA or protect credit card account data. State and local authorities increasingly focus on the importance of protecting individuals from identity theft, with a significant number of states enacting laws requiring businesses to meet minimum cyber-security standards and notify individuals of security breaches involving personal information. State consumer protection laws may also apply to privacy and security practices related to personally identifiable information, including information related to consumers and care providers. Different approaches to state privacy and insurance regulation and varying enforcement philosophies may materially and adversely affect our ability to standardize our products and services across state lines. See Part I, Item 1A, "Risk Factors" for a discussion of the risks related to compliance with state privacy and security regulations.

Corporate Practice of Medicine and Fee-Splitting Laws. Certain of our businesses function as direct medical service providers and, as such, are subject to additional laws and regulations. Some states have corporate practice of medicine laws prohibiting specific types of entities from practicing medicine or employing physicians to practice medicine. Moreover, some states prohibit certain entities from engaging in fee-splitting practices, which involve sharing in the fees or revenues of a professional practice. These prohibitions may be statutory or regulatory, or may be imposed through judicial or regulatory interpretation. The laws, regulations and interpretations in certain states have been subject to limited judicial and regulatory interpretation and are subject to change. In addition, some states have begun to consider new laws to expand or change the scope of corporate practice of medicine laws. Any such changes could adversely impact how we structure transactions and contract with and support physicians in those states.

Pharmacy and Pharmacy Benefits Management (PBM) Regulations

Optum Rx's businesses include home delivery, specialty and compounding pharmacies, as well as clinic-based pharmacies which must be licensed as pharmacies in the states in which they are located. Certain of our pharmacies must also register with the U.S. Drug Enforcement Administration (DEA) and individual state controlled substance authorities to dispense controlled substances. In addition to adhering to the laws and regulations in the states where our pharmacies are located, we also are required to comply with laws and regulations in some non-resident states where we deliver pharmaceuticals, including those requiring us to register with the board of pharmacy in the non-resident state. These non-resident states generally expect our pharmacies to follow the laws of the state in which the pharmacies are located, but some non-resident states also require us to comply with their laws if pharmaceuticals are delivered within those states. Additionally, certain of our pharmacies which participate in programs for Medicare and state Medicaid providers are required to comply with applicable Medicare and Medicaid provider rules and regulations. Other laws and regulations affecting our pharmacies include federal and state statutes and regulations governing the labeling, packaging, advertising and adulteration of prescription drugs and dispensing of controlled substances. See Part I, Item 1A, "Risk Factors" for a discussion of the risks related to our pharmacy care services businesses.

Federal and state legislation regulating PBM activities affects both our ability to limit access to a pharmacy provider network or remove network providers. Many states limit our ability to manage and establish maximum allowable costs for generic prescription drugs and regulate various pharmacy reimbursement measures. With respect to formulary services, a number of government entities, including CMS, HHS and state departments of insurance, regulate the administration of prescription drug benefits offered through federal or state exchanges. Many states also regulate the scope of prescription drug coverage, as well as the delivery channels to receive such prescriptions, for insurers, MCOs and Medicaid managed care plans. These regulations

could limit or preclude (i) certain plan designs, (ii) limited networks, (iii) use of particular care providers or distribution channels, (iv) copayment differentials among providers and (v) formulary tiering practices.

Legislation seeking to regulate PBM activities introduced or enacted at the federal or state level could impact our business practices with others in the pharmacy supply chain, including pharmaceutical manufacturers and network providers. In addition, organizations like the NAIC periodically issue model regulations while credentialing organizations, like the National Committee for Quality Assurance (NCQA) and the Utilization Review Accreditation Commission (URAC), may establish standards impacting PBM pharmacy activities. Although these model regulations and standards do not have the force of law, they may influence states to adopt their recommendations and impact the services we deliver to our clients.

Consumer Protection Laws

Certain of our businesses participate in direct-to-consumer activities and are subject to regulations applicable to online communications and other general consumer protection laws and regulations such as the Federal Tort Claims Act, the Federal Postal Service Act and the FTC's Telemarketing Sales Rule. Most states also have similar consumer protection laws.

Certain laws, such as the Telephone Consumer Protection Act, give the FTC, the Federal Communications Commission (FCC) and state attorneys general the ability to regulate, and bring enforcement actions relating to, telemarketing practices and certain automated outbound contacts such as phone calls, texts or emails. Under certain circumstances, these laws may provide consumers with a private right of action to enforce those laws. Violations of these laws could result in substantial statutory penalties and other sanctions.

Banking Regulation

Optum Bank is subject to supervision and regulation by the Utah State Department of Financial Institutions, which carries out annual examinations to ensure the bank is operating in accordance with state safety and soundness requirements and performs periodic examinations of the bank's compliance with applicable state banking statutes, regulations and agency guidelines. Optum Bank is also subject to regulation by federal banking regulators, including the Federal Deposit Insurance Corporation (FDIC), which performs annual examinations to ensure the bank is operating in accordance with federal safety and soundness requirements, and the Consumer Financial Protection Bureau, which may perform periodic examinations to ensure the bank is in compliance with applicable consumer protection statutes, regulations and agency guidelines. In the event of unfavorable examination results or an enforcement action from these state or federal agencies, the bank could become subject to civil litigation, increased operational expenses and capital requirements, enhanced governmental oversight, monetary penalties and other sanctions.

Non-U.S. Regulation

Certain of our businesses operate internationally and are subject to regulation in the jurisdictions in which they are organized or conduct business. These regulatory regimes vary from jurisdiction to jurisdiction. In addition, our non-U.S. businesses and operations are subject to U.S. laws regulating the conduct and activities of U.S.-based businesses operating outside the United States, such as the Foreign Corrupt Practices Act (FCPA), which prohibits offering, promising, providing or authorizing others to give anything of value to a foreign government official to obtain or retain business or otherwise secure a business advantage.

COMPETITION

As a diversified health care company, we operate in highly competitive markets across the full expanse of health care benefits and services. Our competitors include organizations ranging from startups to highly sophisticated Fortune 50 global enterprises, for-profit and non-profit companies, and private and government-sponsored entities. New entrants to our markets and business combinations among our competitors and suppliers also contribute to a dynamic and competitive environment. We compete fundamentally on the quality and value we provide to those we serve, which can include elements such as product and service innovation; use of technology; consumer and provider engagement and satisfaction; and sales, marketing and pricing. See Part I, Item 1A, "Risk Factors" for additional discussion of our risks related to competition.

INTELLECTUAL PROPERTY RIGHTS

We have obtained trademark registration for the UnitedHealth Group, Optum and UnitedHealthcare names and logos. We own registrations for certain of our other trademarks in the United States and abroad. We hold a portfolio of patents and have patent applications pending from time to time. We are not substantially dependent on any single patent or group of related patents.

Unless otherwise noted, trademarks appearing in this report are trademarks owned by us. We disclaim any proprietary interest in the marks and names of others.

HUMAN CAPITAL RESOURCES

As of December 31, 2025, we had more than 390,000 employees, of whom nearly 165,000 were clinical professionals.

Our employees are guided by our mission to help people live healthier lives and help make the health system work better for everyone. Our mission and cultural values of integrity, compassion, inclusion, relationships, innovation and performance align with our long-term business strategy to increase access to care, make care more affordable, enhance the care experience and improve health outcomes. Our mission and values attract individuals who are determined to make a difference – individuals whose talent, innovation, engagement and empowerment are critical in our ability to achieve our mission.

We seek to maintain an inclusive environment where people of diverse talents, backgrounds, experiences and perspectives make us better. We promote an inclusive culture and a sense of belonging throughout our organization and operations, including in our talent acquisition and talent management practices; leadership development; careers; learning and skills; and systems and processes. We prioritize equal pay by objectively and regularly evaluating and reviewing our compensation practices by performance, experience, and other relevant measures.

INFORMATION ABOUT OUR EXECUTIVE OFFICERS

The following sets forth certain information regarding our executive officers as of March 2, 2026, including the business experience of each executive officer during the past five years:

Name	Age	Position
Stephen Hemsley	73	Chair and Chief Executive Officer
Wayne DeVeydt	56	Chief Financial Officer
Dr. Patrick Conway	51	Chief Executive Officer, Optum
Erin McSweeney	61	Executive Vice President and Chief People Officer
Timothy Noel	54	Chief Executive Officer, UnitedHealthcare
Thomas Roos	53	Senior Vice President and Chief Accounting Officer
Christopher Zaetta	54	Executive Vice President and Chief Legal Officer and Corporate Secretary

Our Board of Directors elects executive officers annually. Our executive officers serve until their successors are duly elected and qualified, or until their earlier death, resignation, removal or disqualification.

Stephen Hemsley has served as Chief Executive Officer and Chair of the Board of UnitedHealth Group since May 2025. Steve previously served as Non-Executive Chair of the Board from November 2019 to May 2025, Executive Chair of the Board from September 2017 to November 2019, Chief Executive Officer from November 2006 to August 2017, President from May 1999 to November 2014, and Chief Operating Officer from November 1998 to November 2006. He joined the Company in 1997 and has been a member of the Board of Directors since 2000.

Wayne DeVeydt has served as Chief Financial Officer of UnitedHealth Group since September 2025. Prior to joining UnitedHealth Group, Wayne was Managing Director of Bain Capital, a private investment firm, from March 2022 to August 2025. Wayne previously served as Chief Executive Officer, from January 2018 to January 2020, and Executive Chairman of the Board of Directors, from January 2020 to August 2025, of Surgery Partners, an operator of surgical facilities and ancillary services, and Executive Vice President and Chief Financial Officer of Elevance Health (formerly known as Anthem), a health benefits and insurance provider, from 2007 to June 2016.

Dr. Patrick Conway has served as Chief Executive Officer of Optum since May 2025. Previously, Patrick served as Optum Rx's Chief Executive Officer and held numerous leadership roles since joining UnitedHealth Group in February 2020, including service as Chief Executive Officer of Optum Health Care Solutions. Prior to joining UnitedHealth Group, Patrick held prominent senior leadership positions in the private and public sector and clinical settings, including service as Chief Medical Officer and acting administrator at Centers for Medicare and Medicaid Services, and as director of the CMS Innovation Center.

Erin McSweeney has served as Executive Vice President and Chief People Officer of UnitedHealth Group since March 2022. From February 2021 to March 2022, Erin served as chief of staff to UnitedHealth Group's Office of the Chief Executive. From January 2017 to February 2021, she served as Executive Vice President and Chief Human Resources Officer at Optum. Prior to joining UnitedHealth Group, Erin was Executive Vice President and Chief Human Resources Officer for EMC Corporation, an international technology company.

Tim Noel has served as Chief Executive Officer of UnitedHealthcare since January 2025. Previously, Tim served as Chief Executive Officer of UnitedHealthcare's Medicare & Retirement business and held numerous leadership roles since joining UnitedHealth Group from 2007 until January 2025, including serving as Chief Financial Officer and Senior Vice President of federal products for Medicare & Retirement.

Tom Roos has served as Senior Vice President and Chief Accounting Officer of UnitedHealth Group since August 2015. Prior to joining UnitedHealth Group, Tom was a Partner at Deloitte & Touche LLP, an independent registered public accounting firm.

Chris Zaetta has served as Executive Vice President, Chief Legal Officer and Corporate Secretary of UnitedHealth Group since May 2024. Previously, Chris served as Chief Legal Officer of Optum from September 2020 until May 2024. Prior to joining Optum in 2020, Chris was Vice President at Johnson & Johnson, a pharmaceutical company. Chris also held several leadership roles at UnitedHealth Group from May 2011 to September 2019, including Head of Litigation and General Counsel of the organization's government businesses.

ADDITIONAL INFORMATION

Our executive offices are located at 1 Health Drive, Eden Prairie, Minnesota 55344 and 655 New York Avenue, Washington, DC 20001; our telephone number is (800) 328-5979. You can access our website at www.unitedhealthgroup.com to learn more about our company. We make periodic and current reports and amendments available, free of charge, on our website, as soon as reasonably practicable after we file or furnish these reports to the SEC. Information on or linked to our website is neither part of nor incorporated by reference into this Annual Report on Form 10-K or any other SEC filings.

ITEM 1A. RISK FACTORS

CAUTIONARY STATEMENTS

The statements, estimates, projections or outlook contained in this Annual Report on Form 10-K include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). When used in this Annual Report on Form 10-K and in future filings by us with the SEC, in our news releases, presentations to securities analysts or investors, and in oral statements made by or with the approval of one of our executive officers, the words "believe," "expect," "intend," "estimate," "anticipate," "forecast," "outlook," "plan," "project," "should" or similar words or phrases are intended to identify such forward-looking statements. These statements are intended to take advantage of the "safe harbor" provisions of the PSLRA. These forward-looking statements involve risks and uncertainties which may cause our actual results to differ materially from the expectations expressed or implied in the forward-looking statements. Any forward-looking statement in this report speaks only as of the date of this report and, except as required by law, we undertake no obligation to update any forward-looking statement to reflect events or circumstances, including unanticipated events, after the date of this report.

The following discussion contains cautionary statements regarding our business, which investors and others should consider. We do not undertake to address in future filings with the SEC or other communications regarding our business or results of operations how any of these factors may have caused our results to differ from discussions or information contained in our previous filings or communications. In addition, any of the matters discussed below may have affected past, as well as current, forward-looking statements about future results.

Any or all forward-looking statements in this Annual Report on Form 10-K and in any other SEC filings or public statements we make may turn out to be wrong. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. By their nature, forward-looking statements are not guarantees of future performance or results and are subject to risks, uncertainties and assumptions which are difficult to predict or quantify.

The risks and uncertainties discussed below are not the only risks we may face. There may be risks and uncertainties not currently known to us or that we may deem to be immaterial that could materially and adversely affect our business, results of operations, financial position, cash flows and prospects.

Risks Related to Our Business and Our Industry

If we fail to estimate, price for and manage our medical costs or design benefits in an effective manner, the profitability of our risk-based products and services could decline and could materially and adversely affect our results of operations, financial position and cash flows.

Through our risk-based benefit products, we assume the risk of both medical and administrative costs for our customers in return for monthly premiums. The profitability of our products depends in large part on our ability to predict and effectively price for and manage medical costs. Our Optum Health business also enters into fully accountable value-based arrangements with payers. Premium revenues from risk-based products constitute nearly 80% of our total consolidated revenues. Estimates of benefit expense payments involve extensive judgement and are subject to considerable inherent variability. Relatively small differences between predicted and actual medical costs, or utilization rates as a percentage of revenues, have resulted and in the future may result in significant changes in our financial results. If we fail to predict accurately, or effectively price for or manage, the costs of providing care under risk-based arrangements, our results of operations could be materially and adversely affected.

We manage medical costs through underwriting criteria, product design, negotiation of competitive provider contracts and care management programs. Total medical costs are affected by the number of individual services rendered, the cost of each service and the type of service rendered. Although we base the premiums we charge on our estimates of future medical costs over the fixed contract period, many factors may cause, and have previously caused, actual costs to exceed those estimated and reflected in premiums or bids. These factors may include medical cost inflation, increased use of services, increased provider billing intensity, business mix, unexpected differences among new customer populations, increased cost of individual services, costs to deliver care, large-scale medical emergencies, the potential effects of climate change, pandemics, the introduction of new or costly drugs or increases in drug prices, treatments and technology, new treatment guidelines, newly mandated benefits or other regulatory changes and insured population characteristics. Cost increases in excess of our forecasts typically cannot be recovered in the fixed premium period through higher premiums. For Optum Health's fully accountable value-based care, any inability to provide higher-quality outcomes and better experiences at lower costs or to integrate our care delivery models could impact our results of operations, financial positions and cash flows.

In addition, the financial results we report for any particular period include estimates of costs incurred for which claims are still outstanding. These estimates involve an extensive degree of judgment. If these estimates prove inaccurate, our results of operations could be materially and adversely affected.

If we fail to maintain properly the integrity or availability of our data or successfully consolidate, integrate, upgrade or expand our existing information systems, or if our technology products do not operate as intended, our business could be materially and adversely affected.

Our business depends on the integrity and timeliness of the data we use to serve our members, customers and health care professionals and to operate our business. If the data we rely upon to run our businesses is found to be inaccurate, incomplete, outdated or unreliable or if we fail to effectively maintain or protect the integrity of our data and information systems, including systems powered by or incorporating artificial intelligence (AI), we could experience failures in our health, wellness and information technology products; lose existing customers; have difficulty attracting new customers; experience problems in determining medical cost estimates and establishing appropriate pricing; have difficulty preventing, detecting and controlling fraud; have disputes with customers, physicians and other health care professionals; become subject to regulatory sanctions, penalties, investigations or audits; incur increases in operating expenses; or suffer other adverse consequences.

The volume of health care data generated, and the uses of data, including electronic health records, are rapidly expanding. We depend on the integrity of the data in our information systems to implement new and innovative services, automate and deploy new technologies to simplify administrative processes and clinical decision making, price our products and services adequately, provide effective service to our customers and consumers in an efficient and uninterrupted fashion, provide timely payments to care providers, and accurately report our results of operations. In addition, increasing connectivity among technologies and recent trends toward greater consumer engagement in health care require new and enhanced technologies, including more sophisticated applications for mobile devices and new tools and products that leverage AI to improve the customer experience. We anticipate that fast-evolving AI technologies, including generative AI, will play an increasingly important role in our information systems and customer-facing technology products. Our ability to protect and enhance existing systems and develop new systems to keep pace with changes in information processing technology (including AI), regulatory standards and changing customer preferences will require our ongoing commitment of significant development and operational resources. If these commitments fail to provide the anticipated benefits, if we are unable to successfully anticipate future technology developments, or if the cost to keep pace with the technological changes exceeds our estimates, we could be exposed to reputational harm and experience adverse effects on our business.

We may not successfully implement our initiatives to consolidate the number of information systems we operate, upgrade and expand our systems' capabilities, integrate and enhance our systems and develop new systems to keep pace with recent

regulations and changes in information processing technology. Failure to protect, consolidate and integrate our systems successfully could result in higher than expected costs.

Some of our businesses sell and install software products which may contain unexpected design defects or may encounter unexpected complications during installation or when used with other technologies utilized by the customer. A failure of our technology products to operate as intended and in a fully-integrated fashion with other products could materially and adversely affect our results of operations, financial position and cash flows.

Uncertain and rapidly evolving U.S. federal and state, non-U.S. and international laws and regulations related to health data and health information technologies, including those powered by or incorporating AI, may alter the competitive landscape or impose new compliance requirements and could materially and adversely affect the configuration of our information systems and platforms, and our ability to compete in our markets.

If we or third parties we rely on sustain cyberattacks or other privacy or data security incidents resulting in disruption to our operations or the misappropriation or disclosure of protected personal information or proprietary or confidential information, we could suffer a loss of revenue and increased costs, negative operational effects, exposure to significant liability, reputational harm and other serious negative consequences.

We routinely process, store and transmit large amounts of data in our operations, including protected personal information subject to privacy, security or data breach notification laws, as well as proprietary or confidential information relating to our business or third parties. Some of the data we process, store and transmit may be outside of the United States due to our information technology systems and international business operations. We are regularly the target of attempted cyberattacks and other security threats and have previously been, and may in the future be, subject to compromises of the information technology systems we use, information we hold, or information held on our behalf by third parties. For example, we previously reported that our Change Healthcare business, which we had recently acquired, was subject to a cyberattack in 2024, in which the data involved contained protected health information or personally identifiable information.

While we have programs in place to detect, contain and respond to data security incidents and provide employees with awareness training regarding phishing, malware and other cyber threats as a protection against cybersecurity risks and incidents, we expect that we will continue to experience incidents, some of which may negatively affect our business. Further, because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and are increasing in sophistication, in part due to use of evolving AI technologies (including generative AI), and because our businesses are changing as well, we may be unable to anticipate these techniques and threats, timely detect data security incidents or implement adequate preventive measures. Threat actors and hackers have previously been, and may in the future be, able to negatively affect our operations by penetrating our security controls and causing system and operational disruptions or shutdowns. They may access, misappropriate or otherwise compromise protected personal information or our proprietary or confidential information or that of third parties, and may develop and deploy malicious code (including viruses, ransomware and malware, among others) that can attack our systems, exploit security vulnerabilities, and disrupt or shut down our systems and operations. In addition, hardware, software, or applications we develop or procure from third parties may contain defects or other problems which could unexpectedly compromise our information technology ecosystem. Our systems may also be vulnerable to financial fraud schemes, misplaced or lost data, human error, insider threat, malicious social engineering, or other events which could negatively affect the data or financial accounts, proprietary or confidential information relating to our business or third parties, or our operations. There have previously been and may be in the future heightened vulnerabilities due to recently-acquired or non-integrated businesses. We rely in some circumstances on third-party vendors to process, store and transmit large amounts of data for our business. The operations of these vendors are subject to similar risks, but are outside our direct oversight and control.

The costs to eliminate or address these threats and vulnerabilities before or after a cybersecurity incident could be material. We have business continuity and resiliency plans which we maintain, update and test regularly in an effort to contain and remediate potential disruptions from cybersecurity events. If our prevention and remediation efforts are not successful, we may experience operational interruptions, delays, or cessation of service and loss of existing or potential customers. In addition, compromises of our security measures or the unauthorized dissemination of sensitive personal information, proprietary information or confidential information about us, our customers or other third parties, previously and in the future, could expose us or them to the risk of financial or medical identity theft, negative operational impacts, and loss or misuse of this information, result in litigation and liability, including regulatory penalties, for us, damage our brand and reputation, or otherwise harm our business.

If we fail to develop and maintain satisfactory relationships with health care payers, physicians, hospitals and other service providers, our business could be materially and adversely affected.

We depend substantially on our continued ability to contract with health care payers (as a service provider to those payers), as well as physicians, hospitals, pharmaceutical benefit service providers, pharmaceutical manufacturers and other care and service providers at competitive prices. If we fail to develop and maintain satisfactory relationships with health care providers, whether in-network or out-of-network, our failure to do so could materially and adversely affect our business, results of operations,

financial position and cash flows. In addition, some of our activities related to network design, provider participation in networks and provider payments could result in disputes, which may be costly and attract negative publicity.

In any particular market, physicians and health care providers could refuse to contract with us, demand higher payments, or take other actions which could result in higher medical costs, less desirable products for customers or difficulty meeting regulatory or accreditation requirements. In some markets, certain health care providers, particularly hospitals, physician and hospital organizations or multi-specialty physician groups, may have significant market positions which could diminish our bargaining power. In addition, Accountable Care Organizations (ACOs), physician group management services organizations (which aggregate physician practices for administrative efficiency), and other organizational structures adopted by physicians, hospitals and other care providers may change the way in which these providers do business with us and may change the competitive landscape. Such organizations or groups of physicians may compete directly with us, which could adversely affect our business, and our results of operations, financial position and cash flows by impacting our relationships with these providers or affecting the way we price our products and estimate our costs, which might require us to incur costs to change our operations in an effort to mitigate these impacts. In addition, if these providers refuse to contract with us, use their market position to negotiate favorable contracts or place us at a competitive disadvantage, our ability to market products or to be profitable in those areas could be materially and adversely affected.

Our health care benefits businesses have risk-based arrangements with some physicians, hospitals and other health care providers. These arrangements limit our exposure to the risk of increasing medical costs, but expose us to risk related to the adequacy of the financial and medical care resources of the health care providers. To the extent a risk-based health care provider organization faces financial difficulties or otherwise is unable to perform its obligations under the arrangement, we may be held responsible for unpaid health care claims which should have been the responsibility of the health care provider and for which we have already paid the provider. Further, payment or other disputes between a primary care provider and specialists with whom the primary care provider contracts could result in a disruption in the provision of services to our members or a reduction in the services available to our members. Health care providers with which we contract may not properly manage the costs of services, maintain financial solvency or avoid disputes with other providers. They may also fail to provide us with the information we need to effectively conduct our businesses, such as information enabling us to estimate costs of care. Any of these events could have a material adverse effect on the provision of services to our members and our operations.

Some providers that render services to our members do not have contracts with us. In some instances, those providers have disputed and may in the future dispute the payment for these services and may institute litigation or arbitration relying on state and federal laws that define the compensation that must be paid to out-of-network providers in some circumstances.

The success of some of our businesses depends on maintaining satisfactory relationships with employed, affiliated, and independently contracted physicians and joint venture partners. The physicians who practice medicine or contract with our affiliated physician organizations could terminate their provider contracts or otherwise become unable or unwilling to continue practicing medicine or contracting with us. We face and will likely continue to face heightened competition to acquire or manage physician practices or to employ or contract with individual physicians. Our revenues could be materially and adversely affected if we are unable to maintain or expand satisfactory relationships with physicians, to acquire, recruit or, in some instances, employ physicians, or to retain enrollees following physician departures. In addition, our affiliated physician organizations contract with competitors of UnitedHealthcare. Our businesses could suffer if our affiliated physician organizations fail to maintain relationships with or fail to adequately price their contracts with these third-party payer competitors.

Further, physicians, hospitals, pharmaceutical benefit service providers, pharmaceutical manufacturers and certain health care providers are customers of our Optum businesses. Physicians also provide medical services at facilities owned by our Optum businesses. Given the importance of health care providers and other constituents to our businesses, failure to maintain satisfactory relationships with them could materially and adversely affect our results of operations, financial position and cash flows.

If we fail to compete effectively to maintain or increase our market share, including by maintaining or increasing enrollments in businesses providing health benefits, our results of operations, financial position and cash flows could be materially and adversely affected.

Our businesses face significant competition in all of the markets in which we operate. In many geographies or product segments, our competitors have and may continue to have competitive advantages. Our competitive position may also be adversely affected by significant merger and acquisition activity in the industries in which we operate, among both our competitors and suppliers. Consolidation among competitors may make it more difficult for us to retain or increase our customer base, maintain or improve the terms on which we do business with our suppliers, or maintain or increase our profitability.

In addition, our success in the health care marketplace and future growth depends on our ability to develop and deliver innovative and potentially disruptive products and services to satisfy evolving market demands. If we do not continue to

innovate and provide products and services which are useful and relevant to health care payers, consumers and our customers, we may not remain competitive and risk losing market share to existing competitors and disruptive new market entrants. We may face risks from new technologies and market entrants that could affect our existing relationship with health plan enrollees in the affected markets. We could sustain competitive disadvantages and loss of market share if we fail to continue developing innovative care models, including by accelerating the transition of care to value-based models that achieve higher quality outcomes and better experiences at lower costs and expand access to virtual and in-home care. If health care payers or providers are unwilling or unable to enter into value-based agreements with us, we may be unable to successfully establish or maintain the contractual or employment relationships necessary to achieve the quality and cost objectives we have for value-based contracting. Additionally, our competitive position could be adversely affected by any failure to develop and apply innovative technologies and other effective data and analytics capabilities or to provide services to our clients focused on these technologies and capabilities.

Our business, results of operations, financial position and cash flows also could be materially and adversely affected if we do not compete effectively in our markets, if our reputation suffers harm, if we set rates too high or too low in highly competitive markets, if we do not design and price our products properly and competitively, if we are unable to innovate and deliver products and services demonstrating value to our customers, if we do not provide a satisfactory level of services, if membership or demand for other services does not increase as we expect or declines, or if we lose accounts with more profitable products while retaining or increasing membership in accounts with less profitable products.

We are routinely subject to private party and governmental legal actions and investigations, which could damage our reputation and, if resolved unfavorably, could result in substantial penalties or monetary damages and materially and adversely affect our results of operations, financial position and cash flows.

We are routinely made party to a variety of private party and governmental legal actions and investigations related to, among other matters, the design, management and delivery of our product and service offerings. Any failure by us to adhere to the laws and regulations applicable to our businesses could subject us to civil and criminal penalties.

Legal actions to which we are a party have included and in the future could include matters related to health care benefits coverage and payment of claims (including disputes with enrollees, customers and contracted and non-contracted physicians, hospitals and other health care professionals), tort claims (including claims related to the delivery of health care services, such as medical malpractice by personnel at our affiliates' facilities, or by health care practitioners who are employed by us, have contractual relationships with us, or serve as providers to our managed care networks, including as a result of a failure to adhere to applicable clinical, quality and/or patient safety standards), antitrust claims (including as a result of changes in the enforcement of antitrust laws), whistleblower claims (including claims under the False Claims Act or similar statutes), matters related to our use of or alleged failure to adequately safeguard personal information or other proprietary data, claims related to alleged failure of our technology products to operate properly or fairly, contract and labor disputes, tax claims and claims related to disclosure of certain business practices. In addition, some of our pharmacy services operations are subject to clinical quality, patient safety and other risks inherent in the dispensing, packaging and distribution of drugs, including claims related to purported dispensing and other operational errors. We also have been and in the future may be a party to class action lawsuits, including those brought by health care professional groups, consumers and investors. We operate in jurisdictions where contractual rights, tax positions and applicable regulations may be subject to varying degrees of interpretation or uncertainty, and therefore subject to dispute by customers, government authorities or others.

We are largely self-insured with regard to legal actions, including claims of medical malpractice against our affiliated physicians and us. Although we record liabilities for our estimates of the probable costs resulting from self-insured matters, it is possible the level of actual losses will significantly exceed the liabilities recorded. Additionally, physicians and other healthcare providers have become subject to an increasing number of legal actions alleging medical malpractice and general professional liabilities. Even in states that have imposed caps on damages for such actions, litigants are seeking recoveries under theories of liability that might not be subject to the caps on damages. These actions involve significant defense costs and could result in substantial monetary damages or damage to our reputation.

We cannot predict the outcome of significant legal actions in which we are involved. Even in situations where we engage external insurers, our coverage may be disputed or may not be sufficient to cover the entire amount of certain claims. We incur expenses to resolve these matters and current and future legal actions could further increase our cost of doing business, require us to potentially change the way we conduct our business, and materially and adversely affect our results of operations, financial position and cash flows. Moreover, certain legal actions could result in adverse publicity which could damage our reputation and materially and adversely affect our ability to retain our current business or grow our market share in some markets and businesses.

Our increasing use of AI presents legal, regulatory and business risks to our operations, reputation and financial results.

We increasingly rely on technologies powered by or incorporating AI in our internal operations and in the delivery of products and services. While these technologies present opportunities to improve efficiency, enhance customer experience, and optimize clinical and administrative processes, they also entail risks and uncertainties. We have developed and implemented policies and procedures intended to promote and sustain the responsible design, development, and use of these technologies, consistent with industry best practices. However, to the extent an AI system does not operate as intended or produces an inaccurate, incomplete or biased output, the system could impact operations, customer service or other functions and could have an adverse effect on our business, reputation, results of operations, financial position and cash flows.

Our business could suffer, and our results of operations, financial position and cash flows could be materially and adversely affected, if we fail to successfully manage our strategic alliances, or to complete, manage or integrate acquisitions and other significant strategic transactions or relationships.

As part of our business strategy, we frequently engage in discussions with third parties regarding possible investments, acquisitions, divestitures, strategic alliances, joint ventures and outsourcing transactions and often enter into agreements relating to such transactions. If we fail to meet the needs of our alliance or joint venture partners, including by developing additional products and services, providing high levels of service, pricing our products and services competitively or responding effectively to applicable federal and state regulatory changes, our alliances and joint ventures could be damaged or terminated, which in turn could adversely impact our reputation, business and results of operations. Further, governmental actions, such as actions by the FTC or DOJ or comparable non-U.S. regulatory bodies, may affect our ability to complete strategic transactions, which could adversely affect our future growth. If we fail to identify and successfully complete transactions to meet our strategic objectives, including as a result of antitrust regulatory enforcement actions, such as those that have been brought against us in the past, we may be required to expend resources to develop products and technology internally, be placed at a competitive disadvantage or be adversely affected by negative market perceptions, any of which may have a material adverse effect on our results of operations, financial position or cash flows.

Successful acquisitions also require us to effectively, comprehensively and expeditiously integrate the acquired business into our existing operations, including our internal control environment and culture, or otherwise leverage its operations which may present risks different from those presented by organic growth and may be difficult for us to manage. For example, we have experienced and in the future may encounter more acute information technology system vulnerabilities or different litigation risk profiles in recently acquired businesses than we have historically managed. We may be unable to address these vulnerabilities, inadequacies, differences, or failures soon after acquiring a business, which could undermine integration activities, delay launch of acquired products, and increase infrastructure risk. In addition, even with appropriate diligence, pre-acquisition practices of an acquired business have exposed us in the past and may expose us in the future to legal challenges and investigations that could subject us to criminal fines or reputational harm. Even if we are ultimately successful in resolving these matters, defending such claims may be costly and result in negative publicity. If we cannot successfully integrate our acquired businesses and realize contemplated revenue growth opportunities, cost savings and other synergies, our business, prospects, results of operations, financial position and cash flows could be materially and adversely affected.

We are subject to risks associated with public health crises arising from large-scale medical emergencies, pandemics, natural disasters and other extreme events, which have had and could have an adverse effect on our business, results of operations, financial condition and financial performance.

Large-scale medical emergencies, pandemics, natural disasters, public health crises and other extreme events could have a material adverse effect on our business operations, cash flows, financial conditions and results of operations. For example, disruptions in public and private infrastructure resulting from such events could increase our operating costs and impair our ability to provide services to our clients and customers. In addition, as a result of these events, the premiums and fees we charge may not be sufficient to cover our medical and administrative costs, deferred medical care could be sought in future periods at potentially higher acuity levels, we could experience reduced demand for our services, and our clinical and non-clinical workforce could be affected and sustain a reduced capacity to handle demand for care. Public health crises arising from natural disasters, such as wildfires, hurricanes, and snowstorms, or effects of climate change could impact our business operations and result in increased medical care costs. Government enactment of emergency powers in response to public health crises could disrupt our business operations, including by restricting availability of, or our ability to deliver, pharmaceuticals or other medical supplies, and could increase the risk of shortages of necessary items.

Our sales performance will suffer if we do not adequately attract, retain and provide support to a network of independent producers and consultants.

Our products and services are sold in part through nonexclusive producers and consultants for whose services and allegiance we must compete. Our sales could be materially and adversely affected if we are unable to attract, retain and support independent producers and consultants or if our sales strategy is not appropriately aligned across distribution channels. Our relationships

4J

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Where is the facility located?		☒ Nevada ☐ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10)

Section 1: General Information

Facility Name: ArriVent BioPharma, Inc.

Physical Address: 9841 Washingtonian Blvd. Suite 200, Room 232

City: Gaithersburg State: MD Zip: 20878

Mailing Address (if different from physical address): 9841 Washingtonian Blvd. Suite 200

City: Gaithersburg State: Maryland Zip: 20878

Telephone: 732-910-3848 Website: https://arrivent.com

Name of Designated Representative (DR): Aditya Shukla

Licensing Company Email: statelicenses@arrivent.com DR Email: shuklaA@arrivent.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies ☐ Practitioners ☐ Hospitals ☐ Wholesalers ☐ Veterinarians ☒ Others: Specialty Distributors, Specialty Pharmacies	☒ Dangerous Drugs ☐ Controlled Substances ☐ [a]Medical Products (medical devices, equipment, supplies, gases) ☐ Others:	☒ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ☐ Others:

Section 2: ONLY COMPLETE THIS SECTION IF THE COMPANY IS WHOLESALING [a]Medical Products (medical devices, equipment, supplies and gases). Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 3 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

James Kastenmayer
Original Signature (electronic, copies or stamps not accepted)
James Kastenmayer

July 14, 2026
Date

Section 4: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): _____

Corporation Name: ArriVent BioPharma, Inc.

Mailing Address: 9841 Washingtonian Blvd. Suite 200

City: Gaithersburg State: Maryland Zip: 20878

Telephone: 732-910-3848 Email: statelicenses@arrivent.com

Contact Person Name: Aditya Shukla

Date of SEC Registration: 06/23/2021	SEC Registration Number: 0001868279	Stock Exchange Symbol: AVBP

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 10: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale [a]Medical Products (medical devices, equipment, supplies, gases). (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Products (medical devices, equipment, supplies, gases), supply a copy of proof of insurance (NAC 639.6957).** The Medical Products wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 9)				
• **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20NRS%20639.500%20-%20Effective%2001.07.2026%20-%20Wholesaler%20-%20Post%20on%201.26.26.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

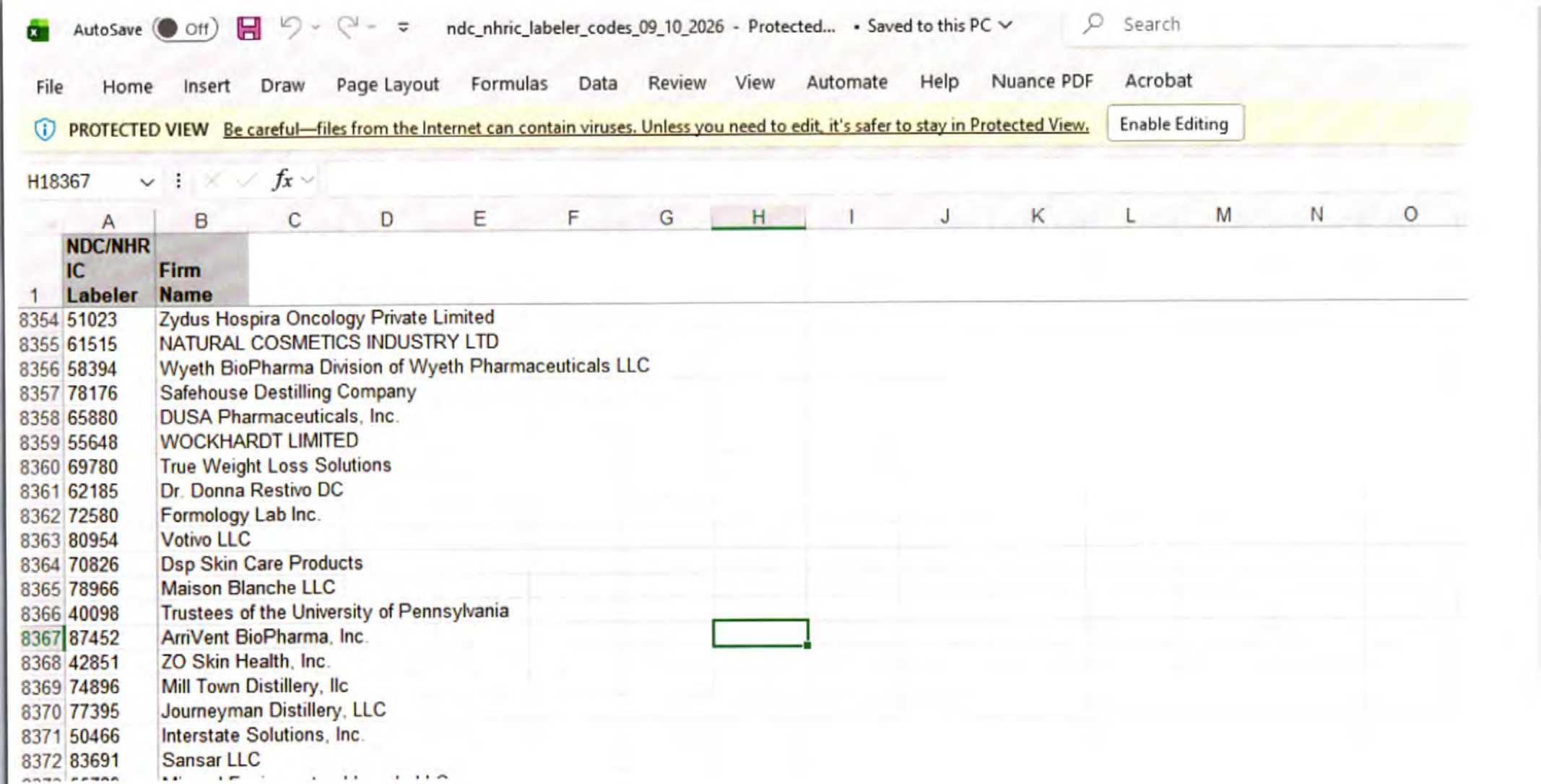
ArriVent BioPharma, Inc.
Facility Name

James Kastenmayer
Print Name of Authorized Person Submitting Application

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

July 14, 2026
Date

Board Use Only	Date Received: 9/3/26	Amount: $1000 Ch. 16033



	A	B
1	**NDC/NHRIC Labeler**	**Firm Name**
8354	51023	Zydus Hospira Oncology Private Limited
8355	61515	NATURAL COSMETICS INDUSTRY LTD
8356	58394	Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC
8357	78176	Safehouse Destilling Company
8358	65880	DUSA Pharmaceuticals, Inc.
8359	55648	WOCKHARDT LIMITED
8360	69780	True Weight Loss Solutions
8361	62185	Dr. Donna Restivo DC
8362	72580	Formology Lab Inc.
8363	80954	Votivo LLC
8364	70826	Dsp Skin Care Products
8365	78966	Maison Blanche LLC
8366	40098	Trustees of the University of Pennsylvania
8367	87452	ArriVent BioPharma, Inc.
8368	42851	ZO Skin Health, Inc.
8369	74896	Mill Town Distillery, llc
8370	77395	Journeyman Distillery, LLC
8371	50466	Interstate Solutions, Inc.
8372	83691	Sansar LLC

Current Date: 20 FEB 2026
Labeler DUNS: 118290045
Labeler Name: ArriVent BioPharma, Inc.
Labeler Code Assigned: 87452

Below is the SPL screenshot in case you need the information.

ArriVent BioPharma, Inc.
NDC/NHRIC LABELER CODE REQUEST

---

verified

Labeler - ArriVent BioPharma, Inc. (118290045) **NDC Labeler Code:** 87452

Contact	Address	Telephone Number
He Wang	Address: 18 Campus Blvd Ste 100 City, State, Zip: Newtown Square, PA, 19073 Country: USA	+1-765-337-3978

Labeler Detail

Name	Address	ID/FEI	Business Operations
ArriVent BioPharma, Inc.	Address: 18 Campus Blvd Ste 100 City, State, Zip: Newtown Square, PA, 19073 Country: USA	118290045	distributes drug products under own private label;Distributes human prescriptio

Revised: 2/2026



Company Information

Company Name: ArriVent Biopharma, Inc.
Address: 9841 Washingtonian Blvd. Suite 200
City, State, Zip: Gaithersburg, MD 20878
Phone: 732-910-3848
Website: https://arrivent.com/
E-mail: statelicenses@arrivent.com

FEIN: 86-3336099
State of Formation: DE
Date Incorporated:04/14/2021
File Number:5841016

Ownership Information

Ownership Information

ArriVent Biopharma, Inc. is a Publicly Traded company on the NASDAQ stock exchange under the symbol AVBP.

Officers

James Kastenmayer, General Counsel
Business Address: 9841 Washingtonian Blvd. Suite 200, Gaithersburg, MD 20878
Business Phone: 628-277-4836
Ownership %:0

Winston Kung, CFO
Business Address: 18 Campus Blvd, Suite 100, Newton Square, PA 19073
Business Phone: 628-277-4836
Ownership %:0

Zhengbin Yao, CEO
Business Address: 18 Campus Blvd, Suite 100, Newton Square, PA 19073
Business Phone: 628-277-4836
Ownership %:0



Description of Operations

ArriVent Biopharma, Inc. is a VirtualManufacturer. ArriVent Biopharma, Inc.'s products are manufactured by a Contract Manufacturer and will be distributed to specialty distributors and specialty pharmacies by their Third-Party Logistics Provider, ICS.

Contract Manufacturer Information:
We are using the following contract manufacturer to produce our product:

CMO Name: Wuxi STA Pharmaceutical Co., Ltd.
Address: No.8 Xinrui Road Xinwu District, Wuxi, China 214028
FDA Establishment Number: 3014784835

Contact Person: Dirk Tormans
Contact Number: +86-198-0231-7354

CMO (Packager) Name: Sharp Packaging Services, LLC
Address: 22-23 Carland Road, Conshohocken, PA 19428
FDA Establishment Number: 2518332

Contact Person: Rhonda Wenner
Contact Number: 484-934-6144

Wuxi STA Pharmaceutical Co., LTD manufactures ArriVent Biopharma, Inc.'s product and Sharp Packaging Services, LLC packages finished product. At no time does Wuxi STA Pharmaceutical Co., LTD or Sharp Packaging Services, LLC own the product, contract with ArriVent Biopharma, Inc.'s customers, invoice, nor sell a ArriVent Biopharma, Inc. product. ArriVent Biopharma, Inc.'s products are not Controlled Substances.

Labeler Code:
87452

Third Party Logistic information:

For distribution into the commercial supply channels, ICS acts as ArriVent Biopharma, Inc.'s Third Party Logistics (3PL) provider to manage the storage and distribution of ArriVent Biopharma, Inc.'s product-throughout the United States. ICS 's address is:

ICS
167 International Blvd Ste A, Brooks, KY 40109
Michael Lamb – Contact Person

ArriVent Biopharma, Inc has 15 employees working on site during normal business hours.

ArriVent Biopharma, Inc.'s hours of operation are 9:00 am – 5:00pm Monday through Friday.

ArriVent Biopharma, Inc.'s records are stored at 3PL and electronically at ArriVent Biopharma, Inc.

ArriVent Biopharma, Inc.'s facility square footage is 195 .

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ARRIVENT BIOPHARMA, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF JUNE, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "ARRIVENT BIOPHARMA, INC." WAS INCORPORATED ON THE FOURTEENTH DAY OF APRIL, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.



C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5841016 8300

SR# 20263366641

Authentication: 204202221

Date: 06-11-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

DISTRIBUTOR REGISTRATION

STATE OF MARYLAND
DEPARTMENT OF HEALTH

209484

Maryland Board of Pharmacy

4201 Patterson Avenue
Baltimore, Maryland 21215

Arrivent Biopharma, Inc.
9841 Washingtonian Blvd
Suite 200
Gaithersburg MD 20878

THE MARYLAND STATE BOARD OF PHARMACY CERTIFIES THAT
Arrivent Biopharma, Inc.
IS A REGISTERED Active
Distributor (exp.: 05/31/2027)

In accordance with the Health Occupations Article of the Annotated Code of Maryland

LIC. REG. PERM. NO.	EXPIRATION DATE
D07923	05/31/2027

SIGNATURE OF BEARER

209484

State of Maryland

209484

DEPARTMENT OF HEALTH

THE MARYLAND STATE BOARD OF PHARMACY
CERTIFIES THAT Arrivent Biopharma, Inc.
IS A REGISTERED Active
Distributor (exp.: 05/31/2027)

SIGNATURE OF BEARER

IN ACCORDANCE WITH THE HEALTH OCCUPATIONS ARTICLE OF THE ANNOTATED CODE OF MARYLAND

LIC. REG. PERM. NO.	EXPIRATION DATE
D07923	05/31/2027

SECRETARY MDH

WHERE REQUIRED BY LAW THIS MUST BE CONSPICUOUSLY DISPLAYED IN OFFICE TO WHICH IT APPLIES

Distributor Change of Information

A Distributor must report changes in their names, addresses, place of employment or other contact information in order to receive renewal notices, newsletters and other important information. A copy of a legal document, such as a Marriage Certificate, must accompany name changes.

To report changes, submit a completed Change of Information form. The form may be downloaded from the Board's website at http://dhmh.maryland.gov/pharmacy/Pages/ChangeRequest.aspx, or contact the Board to have the form sent to you.

Return the completed form by mail, fax or email to:

Maryland Board of Pharmacy
P.O. Box 2051
Baltimore, Maryland 21203-2051
Toll Free: (800)-542-4964 Fax: (410) 358-6207
Email: dhmh.mdbop@maryland.gov

ArriVent BioPharma

9841 Washingtonian Blvd
Suite 200, Room 232
Gaithersburg, MD 20878

Office employee list:

- Diana Atwell
- Laura Lorio
- Jim Kastenmayer
- Adi Shukla
- Jiali Du
- Xiangyang Wang

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For The Transition Period From To

Commission file number: 001-41929

ARRIVENT BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**86-3336099**
(State of Other Jurisdiction of incorporation or Organization)	(I.R.S. Employer Identification No.)
18 Campus Boulevard Suite 100, Newtown Square, PA	**19073**
(Address of principal executive offices)	(Zip Code)

(628) 277-4836
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name Of Each Exchange On Which Registered**
Common Stock, $0.0001 Par Value per Share	**AVBP**	**Nasdaq Global Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically; every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.0405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price of the shares of common stock on The Nasdaq Global Market on June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter), was $762,664,165.

The number of shares of registrant's common stock outstanding as of March 4, 2026 was 44,201,622.

Documents Incorporated by Reference

The information required by Part III of this Annual Report on Form 10-K, to the extent not set forth herein, is incorporated herein by reference from the registrant's definitive proxy statement relating to the Annual Meeting of Stockholders to be held in 2026, which definitive proxy statement shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

TABLE OF CONTENTS

	Page
PART I	
Item 1. Business	5
Item 1A. Risk Factors	62
Item 1B. Unresolved Staff Comments	136
Item 1C. Cybersecurity	136
Item 2. Properties	138
Item 3. Legal Proceedings	138
Item 4. Mine Safety Disclosures	139
PART II	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	139
Item 6. [Reserved]	140
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	140
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	150
Item 8. Financial Statements and Supplementary Data	150
Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	151
Item 9A. Controls and Procedures	151
Item 9B. Other Information	152
Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	152
PART III	
Item 10. Directors, Executive Officers and Corporate Governance	153
Item 11. Executive Compensation	153
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	153
Item 13. Certain Relationships and Related Transactions, and Director Independence	153
Item 14. Principal Accountant Fees and Services	153
PART IV	
Item 15. Exhibits and Financial Statement Schedules	154
Item 16. Form 10-K Summary	156
Signatures	157

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (Annual Report) contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, plans for our product candidates, planned preclinical studies and clinical trials, results of clinical trials, future research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the timing, progress and results of preclinical studies and clinical trials for our product candidates, including our product development plans and strategies;
- estimates of our addressable market, market growth, future revenue, key performance indicators, expenses, capital requirements and our needs for additional financing;
- our ability to obtain funding for our operations;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- the timing or likelihood of regulatory filing and approvals;
- the commercialization of our product candidates, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- developments relating to our competitors and our industry;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing;
- our ability to source sufficient clinical product for our clinical trials and, if our product candidates are approved and commercialized, commercial product;
- the impact of tariffs and changes in economic policies, volatility in inflation, volatility in interest rates, or market disruptions on our business; and
- our financial performance.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the "Risk Factors" section and elsewhere in this Annual Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject and are based on information available to us as of the date of this Annual Report. Although we believe such information forms a reasonable basis for the expectations reflected in the forward-looking statements, such information may be limited or incomplete, and we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report to conform these statements to new information, actual results or to changes in our expectations, except as required by law.

You should read this Annual Report and the documents that we reference in this Annual Report and have filed with the Securities and Exchange Commission (SEC) as exhibits to this Annual Report with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

This Annual Report includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Such data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the markets in which we operate and intend to operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions and estimates.

This Annual Report contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PART I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company dedicated to the identification, development and commercialization of differentiated medicines to address the unmet medical needs of patients with cancers. We seek to utilize our team's deep drug development experience to maximize the potential of our lead product candidate, firmonertinib, and advance a pipeline of novel therapeutics, such as next-generation antibody drug conjugates, including ARR-217 (MRG007), through approval and commercialization in patients suffering from cancer, with an initial focus on solid tumors. Firmonertinib is currently being evaluated in multiple clinical trials across a range of epidermal growth factor receptor (EGFR) mutations (EGFRm) in non-small cell lung cancer (NSCLC). We are conducting a pivotal Phase 3 clinical trial of firmonertinib in treatment naive, or first-line, patients with locally advanced or metastatic EGFRm NSCLC with exon 20 insertion mutations and a pivotal Phase 3 clinical trial of firmonertinib in first-line patients with locally advanced or metastatic EGFRm NSCLC with P-loop and-alpha-c-helix compressing (PACC) mutations. We are conducting a Phase 1 clinical trial of ARR-217 in patients with unresectable locally advanced or metastatic solid tumors.

We received Breakthrough Therapy Designation (BTD) for firmonertinib for first line EGFRm NSCLC with exon 20 insertion from the U.S. Food and Drug Administration (FDA) in October 2023, and Orphan Drug Designation for treatment of NSCLC with EGFRm or human epidermal growth factor receptor 2 (HER2) mutations or human epidermal growth factor receptor 4 (HER4) mutations in February 2024. A product candidate can receive BTD if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have received BTD, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for development, although BTD may not result in a faster development process, review or approval and does not increase the likelihood that the product candidate will ultimately receive FDA approval for any indication.

In 2021, we licensed from Shanghai Allist Pharmaceuticals, Co. Ltd (Allist) the right to develop and commercialize firmonertinib worldwide, with the exception of greater China, which includes mainland China, Hong Kong, Macau and Taiwan. Firmonertinib is an investigational, novel, EGFR mutant-selective tyrosine kinase inhibitor (TKI) that we are developing for the treatment of NSCLC patients across a broader set of EGFR mutations (EGFRm) than are currently served by approved EGFR TKIs. Firmonertinib is currently only approved and commercially distributed by Allist in China as a first-line therapy to treat classical EGFRm NSCLC. The FDA has not approved firmonertinib for any use. We selected firmonertinib for global development against nonclassical, or uncommon, mutations based on preliminary reductions in tumor size observed in seven out of ten patients with EGFR exon 20 insertion mutations treated with firmonertinib in the ongoing Phase 1b clinical trial, the FAVOUR trial, conducted by Allist in China, and preclinical activity in PACC mutations, each a subtype of uncommon mutation. In a subsequent interim data readout from the FAVOUR trial of firmonertinib administered at 240 mg once daily in first-line patients with locally advanced or metastatic EGFRm NSCLC with exon 20 insertion mutations, 79% of patients (n=22 out of 28 patients) were observed to experience a reduction in tumor size of at least 30%. In a final analysis from the Phase 1b FURTHER trial of firmonertinib, which included a cohort of EGFRm NSCLC with PACC mutations, we observed 16.0 months median progression free survival (mPFS) with firmonertinib 240 mg in first-line, confirmed overall response rate (cORR) 68.2% (n=15 out of 22 1L patients at 240mg) and duration of response (DOR) 14.6 months, and confirmed CNS (central nervous system) responses with firmonertinib including complete responses (CRs).

As one of the most prevalent cancers in the world, lung cancer imposes a significant global burden on human health, and EGFRm NSCLC represents a significant proportion of those affected. Despite progress in the therapeutic landscape for EGFRm NSCLC, many patients, particularly those with uncommon mutations, such as exon 20 insertions or PACC mutations, are underserved by existing treatments. In an interim data readout from the FAVOUR trial of firmonertinib administered at 240 mg once daily in first-line patients with locally advanced or metastatic EGFRm NSCLC with exon 20 insertion mutations, 79% of patients (n=22 out of 28 patients) were observed to experience a reduction in tumor size of at least 30% from the baseline in a patient without evidence of progression as measured by Response Evaluation

Criteria in Solid Tumors (RECIST) 1.1 criteria. This measurement of reduction is the threshold in this trial for a partial response and for inclusion in determination of the overall response rate (ORR), which is the primary endpoint of this trial In the same interim data readout, those 79% of patients were observed to experience a 15.2 month median DOR. Interim results may not be indicative of final results; however, we believe these interim clinical results underscore firmonertinib's potential in patients whose tumors contain an uncommon EGFRm.

We are currently conducting a pivotal Phase 3 clinical trial, the FURVENT clinical trial, in first-line locally advanced or metastatic non-squamous EGFRm NSCLC patients with exon 20 insertion mutations and we expect topline data from this trial in mid-2026. Additionally, we are conducting a pivotal Phase 3 clinical trial, the ALPACCA clinical trial, in first-line locally advanced or metastatic non-squamous EGFRm NSCLC patients PACC mutations. In September 2025, our final Phase 1b PACC data reported 68.2% of patients (n=15 out of 22 1L patients at 240 mg) were observed to experience a confirmed reduction in tumor size of at least 30% from the baseline without evidence of progression as measured by RECIST 1.1 criteria. The confirmed mPFS in these patients was 16.0 months.

Since our inception in 2021, we have assembled a robust oncology pipeline by leveraging our global network and our experience in business development transactions. In 2021, we licensed from Allist the right to develop and commercialize firmonertinib worldwide, with the exception of greater China, which includes mainland China, Hong Kong, Macau and Taiwan. Also in 2021, we entered into a research collaboration, as amended, with Aarvik Therapeutics, Inc. (Aarvik) to leverage its proprietary multi-target, multivalent, site-specific conjugation antibody platform to discover next-generation antibody drug conjugates (ADCs) with improved activity and safety over single target bivalent ADCs. In 2024, we entered into a collaboration agreement with Jiangsu Alphamab Biopharmaceuticals Co., Ltd. (Alphamab), a wholly owned subsidiary of Alphamab Oncology, to discover, develop and commercialize novel ADCs for the treatment of cancers globally, with the exception of greater China, which includes mainland China, Hong Kong, Macau and Taiwan. In January 2025, we entered into an Exclusive License Agreement (the Lepu Biopharma Agreement) with Lepu Biopharma Co. Ltd. (Lepu Biopharma) pursuant to which Lepu Biopharma granted us the right to develop and commercialize ARR-217 (MRG007), a CD-H17-targeting ADC for gastrointestinal cancers outside greater China, which includes mainland China, Hong Kong, Macau, and Taiwan.

We plan to continue to engage in business development activities to source additional innovative therapeutics in areas currently underserved by approved therapies. This broader strategy includes evaluating research collaborations, partnerships and licensing arrangements intended to expand our development pipeline of differentiated and next-generation oncology assets. The following table summarizes our current pipeline indicating the most advanced stage of development:



NSCLC: non-small cell lung cancer; EGFR: epidermal growth factor receptor; PACC: P-loop alpha-c helix compressing; TKI: tyrosine kinase inhibitor; BTD: Breakthrough Therapy Designation; ADC: Antibody Drug Conjugate; GI Tumors: gastrointestinal tumors; 1L: First-line therapy; Global Ex-China: Worldwide, except mainland China, Hong Kong, Macau and Taiwan.

Currently approved EGFR TKIs have achieved considerable commercial success and have become the standard of care for patients with NSCLC with classical EGFRm which comprise approximately 69% of all EGFRm NSCLC patients. However, many of these therapies, including AstraZeneca plc's (AstraZeneca) third-generation EGFR TKI, osimertinib (TAGRISSO®), are minimally active against or not approved for use in a significant portion of NSCLC patients with uncommon EGFRm. This unmet need leaves many EGFRm NSCLC patients with few effective treatment options. Firmonertinib is currently approved and commercially distributed by Allist in China as a first-line therapy to treat classical EGFRm NSCLC. However, firmonertinib was designed to have strong inhibitory activity, not only against classical EGFRm, but also against uncommon EGFRm, such as exon 20 insertion and PACC mutations which together account for approximately 22% of EGFRm NSCLC.

To date, firmonertinib has been evaluated in multiple clinical trials with an aggregate patient population of over 1,000 patients against a broad range of EGFRm NSCLC, including both classical and uncommon EGFRm. Based on the results of preclinical and clinical trials conducted to date, we believe that firmonertinib has the potential to retain many of the key advantages of third-generation EGFR TKIs compared to first- and second-generation EGFR TKIs, including overcoming T790M mutations that confer resistance to earlier generation TKIs, while also targeting a broader set of EGFRm. In 2022, Allist reported the results of its FURLONG clinical trial, a double blind, placebo-controlled Phase 3 clinical trial of firmonertinib in first-line NSCLC patients with classical EGFRm. In FURLONG, firmonertinib was compared with the first-generation EGFR TKI, gefitinib, and demonstrated superior progression free survival (PFS) over gefitinib, showing a median PFS of 20.8 months versus 11.1 months for gefitinib. Firmonertinib's ability to cross the blood-brain barrier was also demonstrated in this clinical trial with a central nervous system (CNS) metastases specific ORR, which measured reduction of tumor size of at least 30% in brain metastases if present at the start of therapy, of 91% versus 65% for gefitinib. Based on observed clinical activity against exon 20 insertions in the FAVOUR clinical trial and observed activity against PACC mutations in the FURTHER clinical trial, we believe firmonertinib is potentially differentiated from third-generation EGFR TKIs approved for classical EGFRm NSCLC.

In the United States and the European Union, standard of care for first-line therapy in EGFRm NSCLC involving exon 20 insertion mutations is platinum-based chemotherapy with pemetrexed with or without amivantamab. These regimens have significantly lower response rates and DOR compared to results achieved in first-line patients with classical EGFRm who can be treated with approved third-generation EGFR TKIs. Over 9% of EGFRm NSCLC patients are estimated to have exon 20 insertion mutations. However, amivantamab appears to lack brain penetrance to effectively treat brain metastasis. In March 2024 and July 2024, amivantamab in combination with chemotherapy, was approved in the United States and Europe, respectively, for first line EGFRm NSCLC patients with exon 20 insertion mutations. However, amivantamab is an intravenously administered biologic lacking the advantages of oral therapies. Furthermore, amivantamab is being dosed in combination with chemotherapy in this setting with chemotherapy associated toxicities. We believe firmonertinib, if approved, has the potential to become a chemotherapy-free oral regimen in first-line EGFRm NSCLC patients with exon 20 insertion mutations given the clinical data generated in this patient population to date.

Guidelines employing TKIs for the treatment of many of the PACC EGFRm are not established and, as a result, chemotherapy is often used as the default course of therapy, offering limited efficacy and introducing chemotherapy-related toxicity. Afatinib (GILOTRIF®), a second-generation TKI, is also used in some patients, but has an unfavorable safety profile and is not brain penetrant. Osimertinib is frequently used in some patients, but the activity of osimertinib in such patients is less than its activity in patients with classical EGFRm NSCLC. Over 12% of EGFRm NSCLC patients are estimated to have PACC mutations. If approved, we believe firmonertinib has the potential to become a leading treatment option for first-line EGFRm NSCLC patients with PACC mutations based on firmonertinib's preclinical and clinical activity observed against these mutations and the evaluation of firmonertinib in multiple clinical trials.

Our Firmonertinib Development Initiative

We have designed a robust global clinical development plan across a broad spectrum of EGFRm NSCLC patient populations for which we believe firmonertinib will have a differentiated profile compared to currently available treatments. The following table describes the key planned and ongoing clinical trials of firmonertinib conducted by us or our collaboration partners:

						EGFRm Patient Population							
						Exon 20			PACC			Classical	
Trial	Phase	Trial Differentiator	Status	Next Anticipated Milestone	Geography	Adj	1L	2L+	Adj	1L	2L+	1L	2L+
FURVENT	Phase 3	Pivotal trial for Exon 20	Completed Enrollment	Topline data in early 2026	Global		✓						
FAVOUR	Phase 1b	Proof of Concept (PoC) in Exon 20	Completed Enrollment	Publication in 2026	China*		✓	✓					
ALPACCA	Phase 3	Pivotal Trial for PACC	Enrolling		Global					✓			
Adjuvant*	Phase 2	Pivotal trial for Uncommon Mutations	Planned		Global	✓			✓				
FURLONG	Phase 3	Pivotal trial for Classical	Completed Study		China*							✓	

*Allist sponsor; 1L: First-Line Therapy; 2L+: Second-line or greater therapy.

FURVENT — Our Ongoing Phase 3 Clinical Trial in First-Line Non-Squamous Locally Advanced or Metastatic EGFRm NSCLC Patients with Exon 20 Insertion Mutations

We enrolled 398 patients in FURVENT, a global, pivotal Phase 3 clinical trial of firmonertinib in first-line non-squamous locally advanced or metastatic NSCLC patients with exon 20 insertion mutations being conducted jointly with Allist. Our FURVENT clinical trial is designed to assess the safety and efficacy of firmonertinib administered at either 160 mg or 240 mg, once-daily as compared to platinum-based chemotherapy with pemetrexed, the current first-line standard of care. The primary endpoint of this study is PFS. We enrolled 398 patients globally, including from sites in the United States, Europe and certain Asian countries including China. We expect topline data from our FURVENT clinical trial in mid-2026.

FAVOUR — Phase 1b Clinical Trial in NSCLC Patients with EGFR Exon 20 Insertion Mutations

The FAVOUR clinical trial is an ongoing 90-patient Phase 1b clinical trial being conducted by Allist in China that is intended to assess the safety and efficacy of firmonertinib in locally advanced or metastatic NSCLC patients who have EGFR exon 20 insertion mutations. First-line patients receive 240 mg firmonertinib once daily. Patients that have received prior treatment are randomized to receive either 160 mg or 240 mg of firmonertinib once daily. Initial data obtained through June 15, 2023 showed a confirmed ORR (defined as a reduction in tumor size of at least 30% from the baseline in a patient without evidence of progression), among patients evaluable as of that date of 79% among the treatment-naïve patients cohort, 46% among the pretreated 240 mg cohort and 39% in the pretreated 160 mg cohort. Median DOR was 15.2 months in treatment-naïve patients, 13.1 months in the 240 mg pretreated cohort and 9.7 months in the 160 mg pretreated cohort. Firmonertinib was observed to be generally well tolerated in all clinical trial cohorts to date with a low rate of discontinuation due to treatment-related adverse events (TRAEs). As of June 15, 2023, treatment related serious adverse events (TRSAEs) were observed in 6 out of 86 of the treated patients and 2 out of 86 patients discontinued participation in the trial as a result of TRAEs.

FURTHER — Our Ongoing Phase 1b Clinical Trial in NSCLC Patients with EGFR Activating Mutations including PACC Mutations

We have completed enrolling patients in FURTHER, an ongoing, global Phase 1b dose escalation and expansion clinical trial being conducted jointly with Allist. It is intended to evaluate the safety, pharmacokinetics and preliminary anti-tumor activity of once-daily firmonertinib when used in patients with NSCLC involving locally advanced or metastatic disease that have previously received systemic therapy and whose tumors contain EGFR activating mutations. Anti-tumor activity is measured by confirmed complete response, defined as the disappearance of all target lesions, or partial response, defined as at least a 30% decrease in target lesions in the absence of a complete response, relative to the total number of patients. The pharmacokinetics, adverse events, serious adverse events, and observed anti-tumor activity in the exon 20 patients of firmonertinib in the clinical trial to date are consistent with those observed in the FAVOUR clinical trial conducted in China. The FURTHER clinical trial includes a cohort of 60 patients with a PACC EGFRm who are TKI treatment-naïve, and has been fully enrolled. In September 2025, we announced our final data from the FURTHER trial of firmonertinib in first-line patients with locally advanced or metastatic EGFRm NSCLC with PACC mutations. In this final readout, patients treated with 240 mg of firmonertinib were observed to experience 16.0 months mPFS and 14.6 months median duration of response. Further, 68.2% of patients treated in first-line at 240 mg and 43.5% of patients treated in first-line at 160 mg were observed to experience a reduction in tumor size of at least 30% from the baseline in a patient without evidence of progression as measured by RECIST 1.1 criteria, which measurement of reduction is the threshold in this trial for determination of the ORR. In addition, 47% (n=8/17) of patients with brain metastases at baseline were observed to experience a confirmed response utilizing modified RECIST 1.1 and 42.9% (n=6/14) of first line patients with brain metastases at baseline were observed to experience a reduction in tumor size of at least 30% from the baseline in a patient without evidence of progression as measured by RECIST 1.1 criteria. Firmonertinib was generally well-tolerated and consistent with interim safety results.

ALPACCA — Our Ongoing Phase 3 Clinical Trial in First-Line Non-Squamous Locally Advanced or Metastatic EGFRm NSCLC Patients with PACC Mutations

In December 2025, we announced the first patient dosed and plan to enroll 480 patients in ALPACCA, a global, pivotal Phase 3 clinical trial of firmonertinib in first-line non-squamous locally advanced or metastatic NSCLC patients with PACC mutations being conducted jointly with Allist. Our ALPACCA clinical trial is designed to assess the safety and efficacy of firmonertinib administered at 240 mg, once-daily as compared to an investigator's choice of osimertinib or afatinib. The co-primary endpoints of this study are ORR and PFS. The study design reflects design elements from the FDA's Project FrontRunner where we have the potential to seek accelerated approval based on ORR and full approval based on PFS.

Planned Adjuvant Study in NSCLC Patients with Uncommon EGFRm, including Exon 20 Insertion and PACC Mutations

The potential for EGFR TKIs that have demonstrated efficacy, safety and tolerability in the metastatic setting to improve disease-free and overall survival when administered in the adjuvant setting has been demonstrated by osimertinib in NSCLC patients with a classical EGFRm. We believe firmonertinib similarly has the potential to improve outcomes when administered as adjuvant therapy to EGFRm NSCLC patients with uncommon EGFRm, as these patients are not eligible for treatment with osimertinib. We intend to participate in a global adjuvant study of firmonertinib in EGFRm NSCLC with uncommon mutations initiated in China, or to conduct a parallel study, depending on results obtained from currently ongoing clinical trials.

FURLONG — Completed Phase 3 Clinical Trial in Classical EGFRm First-Line NSCLC Patients

FURLONG was a 358-patient clinical trial in China conducted by Allist, with results first reported in 2022, which resulted in the approval of firmonertinib in China as a first-line therapy in patients with locally advanced or metastatic NSCLC with classical EGFRm. It was designed to compare the safety and efficacy of once daily dosing of 80 mg firmonertinib to 250 mg gefitinib. Firmonertinib demonstrated clinically meaningful and statistically significant efficacy and a favorable safety profile as compared to the first-generation EGFR TKI gefitinib. Importantly, firmonertinib exhibited superior efficacy in the treatment of CNS metastases, producing a confirmed CNS metastases specific ORR, which measured reduction in tumor size of at least 30% in brain metastases if present at the start of therapy, of 91%

versus 65% for gefitinib among participants with measurable metastatic CNS disease, demonstrating firmonertinib's ability to cross the blood-brain barrier.

Our Antibody Drug Conjugate Collaborations

Consistent with our focus on curating a pipeline of innovative, impactful oncology therapies across modalities, we are advancing next-generation ADCs. ADCs are a promising modality for treating cancer due to their ability to target chemotherapy directly to the tumor cells. We are using Aarvik's proprietary multi-target, multivalent site-specific conjugation antibody platform to discover and develop ADCs with potentially improved activity and safety over single target bivalent ADCs. We identified a preclinical candidate ARR-002 and have initiated Investigational New Drug (IND)-enabling activities. We are also working with Alphamab to leverage their proprietary linker-payload platform and glycan-conjugation technology to discover, develop, and commercialize ADCs for the treatment of cancers. Pursuant to the Lepu Biopharma Agreement, we are developing ARR-217, a novel CDH17-targeting ADC for the treatment of gastrointestinal cancers, which is currently in Phase 1 clinical development.

Our Team and Approach

We were founded and acquired the rights to develop and commercialize firmonertinib worldwide, with the exception of greater China, which includes mainland China, Hong Kong, Macau and Taiwan, in 2021. We believe that our deep expertise in developing oncology drugs, executing cross border business transactions and track record building companies will allow us to expand our portfolio globally, across the oncology landscape. Our co-founder, Chief Executive Officer and Chairman is Zhengbin (Bing) Yao, Ph.D. Prior to ArriVent, Dr. Yao was Chief Executive Officer and Chairman of Viela Bio, Inc. (Viela), which he co-founded in 2018 by licensing a portfolio of therapeutics from AstraZeneca. Viela was subsequently acquired by Horizon Therapeutics plc in 2021 for $3.1 billion. Prior to Viela, Dr. Yao served as Senior Vice President at MedImmune, Inc. and as Senior Vice President and Head of the Immuno-Oncology Franchise at AstraZeneca. Our other co-founder and President of Research and Development is Stuart Lutzker, M.D., Ph.D. Dr. Lutzker joined from Genentech, Inc., where he served in a number of senior Research and Development roles. Most recently, Dr. Lutzker was Vice President and Head of Oncology, Early Clinical Development and oversaw the early clinical phase development of a number of approved products. See "Certain Relationships and Related Transactions, and Director Independence" for more information.

Our team's deep knowledge in oncology has allowed us to identify novel therapeutic programs with strong biologic and scientific rationale that we believe have the potential to offer a differentiated profile to treat cancer patients. Based on our extensive experience working with regulatory agencies, we will pursue assets that we believe have a clear regulatory path to approval. We believe our highly selective in-licensing strategy provides us with high-quality development candidates at preclinical or clinical stages, which, if approved, would have the potential to achieve global commercial success.

While we source candidates from across the globe, our initial focus has been on compounds originally developed in China. We believe that as the world's second-largest pharmaceutical market, with extensive biopharmaceutical research and development capabilities, China provides us with attractive opportunities to in-license innovative therapies that otherwise may not reach global populations. We believe our business development acumen positions us to build a highly competitive pipeline that we are uniquely positioned to bring to global patient communities, beginning with our lead development asset, firmonertinib.

Our Strategy

We intend to become a leading biopharmaceutical company through the identification, development and commercialization of differentiated medicines to address the unmet medical needs of patients with cancers. To accomplish this objective, we plan to:

Maximize the potential of firmonertinib — develop and commercialize firmonertinib for the treatment of a broad array of EGFRm NSCLC indications.

- *Advance firmonertinib through the pivotal Phase 3 FURVENT clinical trial and seek approval as a first-line therapy for non-squamous locally advanced or metastatic EGFRm NSCLC patients with exon 20 insertion mutations.* Exon 20 insertion mutations represent one of the most prevalent uncommon EGFR mutations and make up over 9% of the EGFR NSCLC patient population. While the antibody amivantamab has been approved as second-line therapy and chemotherapy in combination with amivantamab approved in first line therapy, no TKI has been approved as first-line therapy in this indication. We believe the interim data obtained as of June 15, 2023 in the Phase 1b FAVOUR clinical trial, in which patients were administered a 240 mg once-daily dose of firmonertinib, supports the progression of firmonertinib to the next phase of clinical trials. In that interim data readout, 79% of treatment naïve patients (n=22 out of 28 patients) were observed to experience a reduction in tumor size of at least 30% from the baseline in a patient without evidence of progression as measured by RECIST 1.1 criteria. This measurement of reduction is the threshold in this trial for a partial response and for inclusion in determination of the ORR, which is the primary endpoint of this trial. We received Breakthrough Therapy Designation for firmonertinib for the treatment of this disease from the FDA in October 2023, and Orphan Drug Designation for treatment of NSCLC with EGFRm or HER2 mutations or HER4 mutations in February 2024. We do not currently intend to conduct a Phase 2 trial in first-line non-squamous locally advanced or metastatic EGFRm NSCLC patients with exon 20 insertion mutations. We have completed enrollment in our global, pivotal Phase 3 FURVENT clinical trial in first-line non-squamous locally advanced or metastatic EGFRm NSCLC patients with exon 20 insertion mutations and we expect topline data from this clinical trial in mid-2026.
- *Continue to advance firmonertinib through the pivotal Phase 3 ALPACCA clinical trial in EGFRm NSCLC patients with PACC mutations.* We are also advancing the clinical development of firmonertinib as a potential treatment for EGFRm NSCLC patients with PACC mutations. PACC mutations are a distinct set of approximately 70 EGFR-activating mutations, associated with over 12% of EGFRm NSCLC patients. Guidelines employing TKIs for many of the PACC-specific EGFR mutations are not established and, as a result, chemotherapy is often used as the default course of therapy, offering limited efficacy and introducing chemotherapy-related toxicity. Osimertinib is frequently used in some patients, but the activity of osimertinib in such patients is much less than its activity in classical EGFR mutant NSCLC. Afatinib, a second-generation TKI, is also used in some patients, but has an unfavorable safety profile and is not brain penetrant. We are investigating the use of firmonertinib to treat a broad set of PACC mutations the ALPACCA clinical trial based on firmonertinib's observed activity against PACC mutations in preclinical studies together with the evaluation of firmonertinib in multiple clinical trials with an aggregate patient population of over 1000 patients, including over 450 patients outside China. We have initiated our pivotal Phase 3 ALPACCA study with our first patient dosed in December 2025.
- *Evaluate the clinical benefit of treating early-stage disease with firmonertinib.* We also intend to participate in a global registrational Phase 3 clinical trial initiated in China, or to conduct a parallel study, to investigate the potential benefit of firmonertinib in the adjuvant setting in NSCLC patients with uncommon EGFRm that are not eligible for osimertinib such as exon 20 insertion and PACC mutations. We intend to join the adjuvant study of firmonertinib, or to conduct a parallel study, once the EGFRm patient group is further defined based on ongoing clinical trials in the metastatic setting.
- *Employ combination strategies with firmonertinib to overcome and prevent resistance to EGFR TKI in NSCLC involving classical mutations.* Acquired resistance presents an inevitable challenge to longer-term EGFRm NSCLC management. As such, we are evaluating the use of firmonertinib in combination with other potential agents to extend patient benefit in EGFRm NSCLC patients.

Advance novel therapeutic product candidates for unmet medical needs, leveraging innovative platforms and technologies starting with ADCs.

- *Discover and develop differentiated next-generation ADCs for solid tumors.* ADCs are a promising modality for treating cancer due to their ability to target chemotherapy directly to the tumor cells. We have entered into a research collaboration with Aarvik to leverage its proprietary multi-target, multivalent, site-specific conjugation antibody platform to discover ADCs with potentially improved activity and safety over single target bivalent ADCs for oncology indications globally. We identified a preclinical candidate, ARR-002, and have initiated IND-enabling activities. We have also entered into a collaboration with Alphamab to discover, develop and commercialize novel ADCs. We are working with Alphamab to leverage their proprietary linker-payload platform and glycan-conjugation technology to identify novel ADCs for oncology indications globally, except greater China, which includes mainland China, Hong Kong, Macau and Taiwan where Alphamab retains the right to develop and commercialize ADCs. We entered into a license agreement with Lepu Biopharma pursuant to which Lepu Biopharma granted us a right to develop and commercialize ARR-217, an antibody drug conjugate targeting CDH17 for gastrointestinal cancers outside greater China, which is mainland China, Hong Kong, Macau and Taiwan.

  ARR-217 is currently enrolling patients in a Phase 1 clinical study. This is an open-label, multi-center, Phase 1 study to evaluate the safety, tolerability, efficacy, and pharmacokinetics of ARR-217 (MRG007) in patients with unresectable locally advanced or metastatic solid tumors.

Broaden our pipeline through expanded business development initiatives.

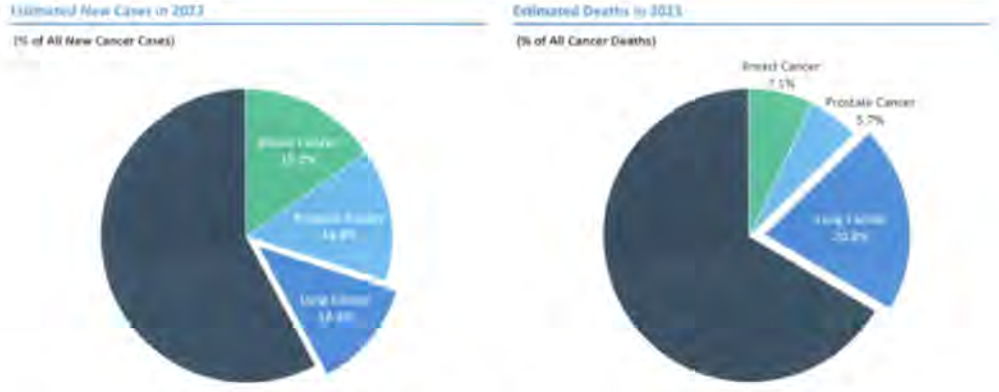
- *Acquire rights to additional therapeutic candidates targeting solid tumors.* We intend to use our demonstrated capabilities in business development to establish additional collaborations and acquire the rights to drug candidates designed to treat solid tumors and address significant unmet medical needs of patients with cancers. While we source candidates from across the globe, our initial focus has been on drugs originally discovered and developed in China for potential commercialization in the United States, the European Union, and other jurisdictions. For programs that we in-license, we plan to pursue a global development strategy to enable approval and commercialization in a broad set of geographies. We remain agnostic as to therapeutic modality, which we believe will expand our access to drug candidates with attractive therapeutic profiles.

- *Track record of establishing collaborations and license agreements.* Since our inception in 2021, we have established four licensing agreements for oncology assets, including our lead product candidate firmonertinib, and the ADC product candidates ARR-217, ARR-002, ARR-421 and ARR-173. We believe in continuing to build our pipeline through sourcing innovation globally and remaining nimble in developing such programs in collaboration with our partners.

Lung Cancer

According to the National Cancer Institute, lung cancer is predicted to account for nearly 250,000 of the two million new cancer diagnoses made in the United States in 2023. Lung cancer ranks behind both breast and prostate cancer in terms of the number of newly diagnosed cases yet is responsible for far more deaths than any other type of cancer, with the estimated 27,000 lung cancer deaths to occur in 2023, more than double the annual number of deaths attributed to colorectal, pancreatic or breast cancer, as illustrated in the chart below. Lung cancer is the cause of approximately 20% of all cancer-related deaths and the 5-year survival rate for advanced lung cancer in the United States is approximately

6%. Worldwide, lung cancer is estimated to be responsible for 2.2 million new cancer cases annually and 1.8 million deaths.

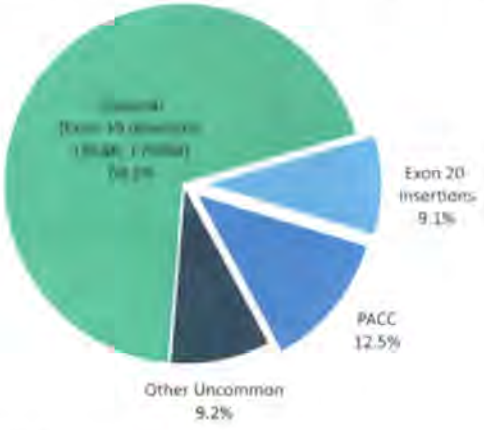


Non-Small Cell Lung Cancer and the EGFR Driver Mutation

Cases of lung cancer are divided into NSCLC and small cell lung cancer, with NSCLC accounting for approximately 85% of all lung cancer diagnoses. NSCLC can be further segregated into two primary classifications: non-squamous cell carcinoma and squamous cell carcinoma. Non-squamous cell carcinoma is the most prevalent type of NSCLC and makes up approximately 77% of all NSCLC cases. Adenocarcinoma is the largest subgroup of the non-squamous NSCLC, constituting 81%. Among the genetic mutations that promote the development of NSCLC, mutational activation of the EGFR gene is among the most common. EGFR is a transmembrane glycoprotein consisting of an extracellular epidermal growth factor binding domain, a hydrophobic transmembrane domain and an intracellular tyrosine kinase domain that regulates signal transduction pathways involved in cellular proliferation. Its mutation results in the constitutive activation of these pathways and uncontrolled growth of the cancer cell. The overall prevalence of the EGFR mutation among NSCLC patients varies widely between different ethnic populations. Approximately 38% of NSCLC patients from Asian countries have an EGFR mutation, while approximately 24% of NSCLC patients in the Americas and approximately 14% of NSCLC patients in Europe have EGFR mutations. EGFR mutations are also more commonly associated with NSCLC patients who have never smoked, as well as women and young adult NSCLC patients. Substantially all NSCLC cases involving an EGFR mutation are non-squamous cell carcinomas.

Numerous EGFR mutations have been identified that cluster within the EGFR kinase domain encoded by exons 18-21 in the EGFR gene. These mutations, which include amino acid insertions, deletions and substitutions, activate EGFR signaling within the tumor cell and can be categorized as either classical or uncommon mutations. Classical mutations involving a deletion in amino acids encoded by exon 19 and another involving a substitution of the amino acid arginine for leucine at codon 858, which is referred to as an L858R mutation, are responsible for approximately 69% of NSCLC patients with an EGFRm. The uncommon mutations may be categorized based on the structural change to the drug binding pocket of the EGFR kinase domain, with the two most frequent groups of uncommon mutations involving an exon 20 insertion or PACC mutations of the EGFR. These two types of uncommon mutations account for approximately 22% of patients with EGFRm NSCLC and the life expectancy for NSCLC patients with uncommon EGFRm, including exon 20 insertion and PACC mutations, is lower. The distribution of patients with EGFR-mutation positive NSCLC is presented below. EGFRm are detected by numerous commercially available FDA-approved DNA tests, either Polymerase Chain Reaction (PCR) or Next Generation Sequencing (NGS), utilizing either tumor tissue or blood samples and testing for EGFRm, as well as other activating gene mutations, is considered standard in the management of NSCLC as per national guidelines such as National Comprehensive Cancer Network (NCCN). We are working with a diagnostics company to develop an FDA-approved NGS test for confirming EGFR exon 20 insertion mutations in our clinical trial and if firmonertinib is approved, we believe it would be indicated for patients with EGFRm as detected by an FDA-approved DNA test.

EGFR activating mutations include both classical and uncommon mutations in the kinase domain



Current Therapeutics and their Limitations

In classical EGFRm NSCLC, the current standard of care for the treatment of locally advanced or metastatic EGFRm NSCLC involves the use of a TKI as first-line therapy. Two first-generation TKIs, gefitinib and erlotinib (TARCEVA®), received initial marketing approval by the FDA in the early 2000s. These drugs, which were designed to competitively bind with EGFR at the ATP-binding site in a reversible manner to block enzymatic activation and downstream signal transduction, provide certain NSCLC patients with EGFRm substantial benefit, offering superior efficacy and safety profiles as compared to chemotherapy. However, durability of response to treatment is limited and virtually all patients with advanced disease acquire resistance, the most common of which involves a T790M substitution mutation. In addition, rash and diarrhea, often severe, are common adverse events (AEs). Efforts to address acquired resistance to first-generation TKIs led to the approval by the FDA of the second-generation TKIs afatinib (GILOTRIF®) in 2013 and dacomitinib (VIZIMPRO®) in 2018, drugs which irreversibly block the tyrosine kinase activity. However, TRAEs are more pronounced than the first-generation designs, which have limited broader clinical application of the second-generation TKIs.

Osimertinib was the first third-generation TKI to receive FDA approval and is currently a standard of care for patients with EGFRm NSCLC involving classical mutations and the related treatment emergent T790M mutation in the majority of countries worldwide. Osimertinib provides an improved AE profile, including a reduction in severe adverse events, compared to the earlier generation EGFR targeted TKIs and displays a greater ability to cross the blood-brain barrier, enabling efficacy against metastases involving the CNS. The ability to treat CNS metastases is of notable importance as patients with EGFR-activating mutations are particularly susceptible to the development of brain metastases, which can occur in up to 70% of patients during the course of their disease. In 2024, amivantamab in combination with lazertinib was approved for the treatment of first-line NSCLC patients with EGFR exon 19 deletions

or exon 21 L858R substitution mutations. Amivantamab is a bispecific antibody and lazertinib is a third-generation EGFR TKI. The key limitations of therapies in EGFRm NSCLC are presented in the graphic below:

Agents	First Approval Year	EGFR Mutation Indications			Key Limitations
		Exon 20 Insertions	PACC	Classical	
Gefitinib, Erlotinib	2003, 2004			✓	Limited efficacy and tolerability, generates T790M resistance mutations
Afatinib	2013		*	✓	Tolerability (rash and diarrhea), low to no brain penetration
Osimertinib	2015			✓	Limited activity outside of Exon 19 deletion and L858R mutations
Amivantamab	2021	✓		✓	IV administration, tolerability (rash and nail toxicity) severe infusion reactions, low to no brain penetration
Mobocertinib	2021	**			Low response rates, tolerability (diarrhea), black box warning for QT prolongation, low to no brain penetration

Table includes approved and disclosed registrational indications
**Afatinib has limited clinical data in patients with 2 of the 70 described PACC mutations.*
***Exclaim-2 study in 1L announced as negative and in July 2024, the FDA withdrew the license for mobocertinib in the United States*
Dacomitinib is also approved in the United States for classical EGFR mutations

There is currently no TKI approved as first-line therapy for NSCLC patients with EGFR exon 20 insertion mutations. Platinum-based chemotherapy with pemetrexed is a standard of care for first-line therapy in this patient population in the United States and the European Union with or without amivantamab. Of particular note, approximately one-third of NSCLC patients harboring EGFR exon 20 insertion mutations have brain metastases at the time of diagnosis, which are mainly treated with radiation therapy, as chemotherapy is less effective in the treatment of brain metastases due to low brain penetration.

In 2021, the FDA granted marketing approval to two therapeutics, mobocertinib, a TKI, and amivantamab, a bispecific antibody, to treat NSCLC patients with exon 20 insertion mutations which have progressed after administration of platinum-based chemotherapy. Both approvals were granted under accelerated approval and continued approval may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Notably, in July 2023, Takeda announced the discontinuation of its Phase 3 clinical trial of mobocertinib as a monotherapy in first-line patients due to futility and subsequently withdrew the drug from the market globally. In August 2023, Johnson & Johnson announced that its Phase 3 trial of amivantamab in combination with chemotherapy in first-line patients met its primary endpoint of PFS when compared to chemotherapy alone. While the FDA approved the use of this combination in this patient population in March 2024, and by the European Commission in July 2024, the use of chemotherapy in combination with amivantamab in the first-line patients may be limited due to the need to combine with intravenous chemotherapy and lack of brain penetration of amivantamab, along with chemotherapy associated toxicities.

A distinct set of approximately 70 uncommon EGFR-activating mutations have been identified that are predicted to alter the orientation of the interior surface of the ATP-binding pocket of the EGFR P-loop or αC-terminal end of the C-helix within the tyrosine kinase domain and are referred to as PACC mutations. Over 12% of patients with EGFRm are estimated to involve PACC mutations and patients diagnosed with PACC mutations have limited treatment options. Guidelines employing TKIs for many of the PACC-specific EGFRm are not established and as a result chemotherapy is used as the default course of therapy in many patients with limited clinical benefit. Osimertinib is frequently used in some patients, but the activity of osimertinib is much less than in classical EGFRm NSCLC. The second-generation TKI

4K

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10)

Section 1: General Information

Facility Name: Belite Bio Holdings Corp.

Physical Address: 12750 High Bluff Drive Ste. 475

City: San Diego State: CA Zip: 92130

Mailing Address (if different from physical address): 12750 High Bluff Drive Ste. 475

City: San Diego State: California Zip: 92130

Telephone: (760) 809 7500 Website: https://belitebio.com

Name of Designated Representative (DR): Ronald Ortiz

Licensing Company Email: licensing@belitebio.com DR Email: ronortiz@belitebio.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical Products (medical devices, equipment, supplies, gases)	☐ Reverse Distributor
☐ Wholesalers		☐ Warehouse
☐ Veterinarians	☐ Others:	☐ Retail pharmacy wholesale distributor
☒ Others: specialty pharmacies		☒ Others: Virtual Manafacturer

Section 2: ONLY COMPLETE THIS SECTION IF THE COMPANY IS WHOLESALING [a]Medical Products (medical devices, equipment, supplies and gases). Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 3 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 4: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 5: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): Belite Bio Inc.

Corporation Name: Belite Bio Holdings Corp.

Mailing Address: 12750 High Bluff Drive Ste. 475

City: San Diego State: California Zip: 92130

Telephone: (760) 809 7500 Email: licensing@belitebio.com

Contact Person Name: Ronald Ortiz

Date of SEC Registration: 12/1/2021	SEC Registration Number: 0001889109	Stock Exchange Symbol: BLTE

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Belite Bio Holdings Corp.
Facility Name

Kelly Kilpatrick
Print Name of Authorized Person Submitting Application

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

7/29/2026
Date

Board Use Only	Date Received: 8/25/26	Amount:

DeLuna, Martha

From: Eric Olson <ericolson@belitebio.com>
Sent: Friday, January 30, 2026 1:31 PM
To: Ron Ortiz
Cc: Paul Leonard; Sibel
Subject: Fw: Labeler Code Request Approved

FYI - labeler code below. Eric

Eric Olson
VP, Strategy
Belite Bio
[redacted]

From: edrls@fda.hhs.gov <edrls@fda.hhs.gov>
Sent: Friday, January 30, 2026 11:55 PM
To: Eric Olson <ericolson@belitebio.com>
Subject: Labeler Code Request Approved

Current Date: 30-JAN-2026
Labeler DUNS: 118663131
Labeler Name: Belite Bio, Inc
Labeler Code Assigned: 87395

The Food and Drug Administration (FDA) has assigned the above Labeler Code to the firm. However, the Labeler Code cannot be used in any drug listing submission until you have confirmed the assignment. To complete this process, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root ID and new version number with the original set ID and the appropriate effective time.

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

Once you have confirmed the assignment, this Labeler Code shall be used to propose the National Drug Code (NDC) for assignment to all drugs you manufacture or distribute for U.S. commercial distribution. The requirements regarding the assignment of an NDC is extensively discussed in Part 207.33 of Title 21 of the Code of Federal Regulations (CFR). The NDC for each drug must be submitted as part of drug listing information submitted to FDA.

Per section 510(j)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR Part 207 registrants that are required to register their establishment with FDA (or Private Label Distributors (PLD) acting as their authorized agent) must list each drug that it manufactures, repacks, relabels, or salvages

for commercial distribution, including the appropriate NDC, no later than 3 calendar days after the initial registration of the establishment. Labeler name, physical address, email address and other contact information, type(s) of activities, and type(s) of drug(s) must be updated within 30 calendar days after any change to that information, § 207.33(c)(2). FDA uses this information for official communication regarding listing.

Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the FD&C Act or other applicable FDA regulations.

Note that receipt of this letter and assignment of an NDC does not denote approval of the establishment or the drug or any other drugs of the establishment, nor does it mean that the drug may be legally marketed.

For additional information please visit Drug Registration and Listing System or reply to this email (edrls@fda.hhs.gov).

Regards,

DRLB

Description of Operations

Belite Bio Holdings Corp. is a Virtual Manufacturer. Belite Bio Holdings Corp.'s products are manufactured by a Contract Manufacturer and will be distributed to Specialty Pharmacies by their Third-Party Logistics Provider, Integrated Commercialization Solutions, LLC (ICS)who is licensed to ship pharmaceutical products into your state.

Contract Manufacturer Information:
We are using the following contract manufacturers to produce our product:

Wuxi STA Pharmaceutical Co., Ltd
No. 8, Xinrui Road, Xinwu District
Wuxi, China 21428
FDA Establishment Number: 3014784835
Contact Person: Hao Yang
Contact Number: +86 (21) 2066-3734

Almac Pharma Services
2661 Audubon Road
Audubon, PA 19403
FDA Establishment Number: 3000214934
Contact Person: Sean McCaig
Contact Number: [redacted]

Wuxi STA Pharmaceutical Co., Ltd manufactures Belite Bio Holdings Corp.'s product and Almac Pharma Services packages the finished product. At no time does Wuxi STA Pharmaceutical Co. or Almac Pharma Services own the product, contract with Belite Bio Holdings Corp.'s customers, invoice, nor sell a Belite Bio Holdings Corp. product. Belite Bio Holdings Corp.'s products are not Controlled Substances.

Labeler Code:
87395

Third Party Logistic information:
For distribution into the commercial supply channels, Integrated Commercialization Solutions, LLC (ICS) acts as Belite Bio Holdings Corp.'s Third Party Logistics (3PL) provider to manage the storage and distribution of Belite Bio Holdings Corp.'s product–throughout the United States. Integrated Commercialization Solutions, LLC (ICS)'s address is:

Integrated Commercialization Solutions, LLC (ICS)
167 International Blvd., Suite A, Brooks, KY 40109

Contact Person: Michael Lamb
Contact Number: [redacted]

Description of Operations (continued)

Belite Bio Holdings Corp. has 39 employees working on site during normal business hours.

Belite Bio Holdings Corp.'s hours of operation are 9:00 am – 5:00pm Monday through Friday.

Belite Bio Holdings Corp.'s records are stored at our 3PL.

Belite Bio Holdings Corp.'s facility square footage is 1562.

Company Information

Company Name: Belite Bio Holdings Corp.
Address: 12750 High Bluff Drive Ste. 475
City, State, Zip: San Diego, CA, 92130
Phone: (760) 809 7500
Website: https://belitebio.com/
E-mail: licensing@belitebio.com

FEIN: 61-1798388
State of Formation: Delaware
Date Incorporated: 6/10/2016
File Number: 6065641

Ownership Information

Belite Bio Holdings Corp. is 100 percent owned by Belite Bio, Inc.
Parent Company Address: PO Box 309, Ugland House, Grand Cayman, KY1-1104, Caymen Islands
Parent Company Phone: (760) 809 7500

Officers

Yu-Hsin (Tom) Lin, Chief Executive Officer
Business Address: 12750 High Bluff Drive, Suite 475
Business Phone: [redacted]

Eric Olson, VP, Global Regulatory Strategy
Business Address: 12750 High Bluff Drive, Suite 475
Business Phone: [redacted]

Kelly Kilpatrick, Chief Commercial Officer
Business Address: 12750 High Bluff Drive, Suite 475
Business Phone: [redacted]

Ting Chen (Jennifer) Wu, Secretary and Treasurer
Business Address: 12750 High Bluff Drive, Suite 475
Business Phone: [redacted]
Ownership %:0

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BELITE BIO HOLDINGS CORP." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTH DAY OF MAY, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. J. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

6065641 8300

SR# 20262276853

Authentication: 203842131

Date: 05-05-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	BELITE BIO HOLDINGS CORP.
Entity No.:	4150471
Registration Date:	05/07/2018
Entity Type:	Stock Corporation - Out of State - Stock
Formed In:	DELAWARE
Status:	Active

The above referenced entity is active on the Secretary of State's records and is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of August 13, 2026.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 489768947

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

[redacted] [redacted]

RE: Licensure Requirements- Manufacturers/Virtual Manufacturers

[redacted]

Tue 6/25/2024 7:05 PM

To [redacted]

[External]

Good Afternoon,

I was requested to respond to your question. Please refer to **Business and Professions Code sec on 4160(h)** which states a drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Sec on 11615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of it own manufacture is exempt from this sec on and sec on 4161.

Therefore, if you are a virtual manufacturer/manufacturer, licensure as a wholesaler or nonresident wholesaler with the California State Board of Pharmacy is not required if you only distribute dangerous drugs and dangerous devices that XXXXXXX has the NDA or manufactures.

However, if XXXXX also distributes dangerous or dangerous devices, which they **are not listed** with the FDA or the California Dept of Public Health, State Food and Drug Branch (CDPH, SFDB), as the manufacturer or does not hold the NDA, then a wholesaler license (if located in CA) or nonresident wholesaler license (outside of CA and within the United States or a territory of the U.S.) is required.

I hope this answers your question. Otherwise, my contact information is below if you have any additional questions.

Sincerely,

[redacted]

Supervising Inspector
California State Board of Pharmacy
(661) [redacted] | FAX (661) 286-1567 | [redacted]

EXEMPT from holding a CA home state license as a Virtual Manufacturer.
See highlighted area on page 225

subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.

(c) "Hospital satellite compounding pharmacy" means an area licensed by the board to perform sterile compounding that is separately licensed by the board pursuant to Section 4127.15 to perform that compounding and is located outside of the hospital in another physical plant that is regulated as a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

4030. Intern Pharmacist

"Intern pharmacist" means a person issued a license pursuant to Section 4208.

4031. Laboratory

"Laboratory" means a research, teaching, or testing laboratory not engaged in the dispensing or furnishing of drugs or devices but using dangerous drugs or dangerous devices for scientific or teaching purposes. Every laboratory shall maintain an established place of business and keep purchase records. Every laboratory shall be subject to the jurisdiction of the board.

4032. License

"License" means and includes any license, permit, registration, certificate, or exemption issued by the board and includes the process of applying for and renewing the same.

4033. Manufacturer

(a) (1) "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer.

(2) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy compounding a drug for parenteral therapy,

pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.

(3) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.

(b) Notwithstanding subdivision (a), as used in Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, "manufacturer" means a person who prepares, derives, manufactures, produces, or repackages a dangerous drug, as defined in Section 4022, device, or cosmetic. Manufacturer also means the holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), or a Biologics License Application (BLA), provided that such application has been approved; a manufacturer's third party logistics provider; a private label distributor (including colicensed partners) for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distributor agent for the manufacturer, contract manufacturer, or private label distributor, whether the establishment is a member of the manufacturer's affiliated group (regardless of whether the member takes title to the drug) or is a contract distributor site.

4034. Outsourcing Facility

"Outsourcing facility" means a facility that meets all of the following:

(a) Is located within the United States of America at one address that is engaged in the compounding of sterile drugs and nonsterile drugs.

4155. Corporate Form Not Required

Nothing in this article shall be construed as requiring the applicant or holder of a pharmacy permit pursuant to Section 4110 to be a pharmacy corporation.

4156. Unprofessional Conduct by Corporation

A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter.

Article 11. Wholesalers, Third-Party Logistics Providers and Manufacturers

4160. Wholesaler or Third-Party Logistics Provider: License Required

(a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) (1) A separate license shall be required for each place of business owned or operated by a wholesaler or third-party logistics provider. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). Each license shall be renewed annually and shall not be transferable. At all times during which a place of business is open for business, at least one designated representative, in the case of a wholesaler, or designated representative-3PL in the case of a third-party logistics provider, shall be present. A wholesaler that only acts as a reverse distributor may use either a designated representative or a designated representative-reverse distributor to fulfill this requirement.

(2) A wholesaler and a third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:

(A) The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.

(B) Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.

(C) Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.

(D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics provider has its own responsible manager responsible for the operations of the third-party logistics provider. The same individual shall not concurrently serve as the responsible manager and the designated representative-in-charge for a wholesaler and a third-party logistics provider licensed at the same place of business.

(E) The third-party logistics provider does not handle the prescription drugs or prescription devices owned by a prescriber.

(F) The third-party logistics provider is not a reverse third-party logistics provider.

(G) The wholesaler is not acting as a reverse distributor.

(d) Every wholesaler shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. As part of its initial application for a license, and for each renewal, each wholesaler shall, on a form designed by the board, provide

identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler license without identification of an approved designated representative-in-charge for the wholesaler. The designated representative-in-charge shall maintain an active license as a designated representative with the board at all times during which he or she is designated as the designated representative-in-charge. A wholesaler that only acts as a reverse distributor may identify and allow a designated representative-reverse distributor to perform in this capacity. That individual shall maintain an active license as a designated representative-reverse distributor.

(e) Each place of business of a third-party logistics provider shall be supervised and managed by a responsible manager. The responsible manager shall be responsible for the compliance of the place of business with state and federal laws governing third-party logistics providers and with the third-party logistics provider's customer specifications, except where the customer's specifications conflict with state or federal laws. As part of its initial application for a license, and for each renewal, each third-party logistics provider shall, on a form designated by the board, provide identifying information and the California license number for a designated representative-3PL proposed to serve as the responsible manager. The proposed responsible manager shall be subject to approval by the board. The board shall not issue or renew a third-party logistics provider license without identification of an approved responsible manager for the third-party logistics provider. The responsible manager shall maintain an active license as a designated representative-3PL with the board at all times during which he or she is designated as the responsible manager.

(f) A wholesaler shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge ceases to act as the designated representative-in-charge, and shall on the same form propose another authorized licensee to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the wholesaler shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

(g) A third-party logistics provider shall notify the board in writing, on a form designed by the board, within 30 days of the date when a responsible manager ceases to act as the responsible manager, and shall on the same form propose another designated representative-3PL to take over as the responsible manager. The proposed replacement responsible manager shall be subject to approval by the board. If disapproved, the third-party logistics provider shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a responsible manager is approved by the board.

(h) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(i) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be required in an amount established by the board as specified in subdivision (f) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by

mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. For purposes of retaining a temporary license, or for purposes of any disciplinary or license denial proceeding before the board, the temporary licenseholder shall not be deemed to have a vested property right or interest in the license.

4160.5. Nonprescription Diabetes Test Devices – Authorized Distributors Posted on Board Website

Within 30 days of the effective date of the act adding this section, a manufacturer of a nonprescription diabetes test device shall make the names of its authorized distributors available on its Internet Web site and shall provide the board with the names of its authorized distributors. Within 30 days of receiving that information from a manufacturer of a nonprescription diabetes test device, the board shall post the names of authorized distributors of nonprescription diabetes test devices on the board's Internet Web site. A manufacturer of a nonprescription diabetes test device shall, within 30 days of making changes to its authorized distributors, update its Internet Web site and inform the board of changes to its authorized distributors. Within 30 days of receiving notice of any change from a manufacturer of a nonprescription diabetes test device, the board shall post the updated list of the manufacturer's authorized distributors on its Internet Web site.

4161. Nonresident Wholesaler or Nonresident Third-Party Logistics Provider; Requirements

(a) A person located outside this state that (1) ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this

N/A

BELIBIO-01 CATHERINEGABRIEL

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 8/5/2026

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

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

PRODUCER	CONTACT NAME:	
NFP Property & Casualty Services, Inc. 45 Executive Drive Plainview, NY 11803	PHONE (A/C, No, Ext): (516) 327-2700	FAX (A/C, No):
	E-MAIL ADDRESS:	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : Federal Insurance Company	20281
INSURED	INSURER B :	
Belite Bio, Inc. Belite Bio Holdings Corp. 12750 High Bluff Dr., Suite 475 San Diego, CA 92130-2083	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

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

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR			3609-8849	7/23/2026	8/1/2027	DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ Excluded
	OTHER:						GLOBAL AGG	$ 3,000,000
A	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	ANY AUTO			7366-69-85	7/23/2026	7/23/2027	BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	UMBRELLA LIAB X OCCUR						EACH OCCURRENCE	$ 10,000,000
	X EXCESS LIAB CLAIMS-MADE			5674-71-22	7/23/2026	8/1/2027	AGGREGATE	$ 10,000,000
	DED RETENTION $						Aggregate	$ 10,000,000
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Products Liability			3609-8848	7/23/2026	8/1/2027	$10,000 Deductible	10,000,000
A	E&O/Professional			3609-8848	7/23/2026	8/1/2027	$10,000 Deductible	5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
**** Please see Remarks Section (Page 2) for additional Coverages. Due to limited space, we are not able to show all policies on above form. ****

CERTIFICATE HOLDER

EVIDENCE OF INSURANCE

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

Catherine Gabriel

ACORD 25 (2016/03) © 1988-2015 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: BELIBIO-01 CATHERINEGABRIEL

LOC #: 1

ACORD

ADDITIONAL REMARKS SCHEDULE

AGENCY		NAMED INSURED
NFP Property & Casualty Services, Inc.		Belite Bio, Inc. Belite Bio Holdings Corp. 12750 High Bluff Dr., Suite 475 San Diego, CA 92130-2083 San Diego
POLICY NUMBER SEE PAGE 1		
CARRIER SEE PAGE 1	NAIC CODE SEE P 1	EFFECTIVE DATE: SEE PAGE 1

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 25 FORM TITLE: Certificate of Liability Insurance

Contractual Insurance Requirements

The attached Certificate of Insurance is provided as part of our service to our client, the Insured. If special endorsements have been provided, they are indicated and attached. You may find that these documents do not comply with all the terms and conditions of the underlying contract between the Certificate Holder and the Insured due to the insurance company's insuring conditions, limitations, exclusions and other terms. If you have any questions, please contact the agent listed below:

NFP Property & Casualty Services, Inc.
CA License #0F15715
Telephone: (408) 792-5400
Fax: (408) 792-3670

******** Additional Coverages ********

Crime Policy #ELU211861-26
Carrier: XL Specialty Insurance Company
Term: 07/15/2026 - 08/01/2027
Limit: $5,000,000 (Includes Client's Property/3rd Party)
Deductible: $25,000

Cyber Policy #ESP0040926915
Carrier: Underwriter's at Lloyds, London
Term: 07/28/2026 - 08/01/2027
Limit: $5,000,000
Deductible: $50,000

Excess Product Liability Policy #TBD
Carrier: Endurance Risk Solutions Assurance Co.
Term: 07/23/2026 - 08/01/2027
Limit: $10,000,000 excess of $10,000,000
TOTAL PRODUCT LIABILITY LIMIT (all policies combined): $20,000,000

© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

Employee Name
Adelstein,Herbert
Beres,Adam Andrew
Bishop,Diane
Boreham,Sibel
Bush,Michael
Clark,Yvonne
Crump,Tiffany Renee
Delgado,Moises
Engelmeier,Jacob J
Farmer,Donald
Ferriola,Vincent F.
Ferris,Ardelle
Fisher,Amy k
Flagg,Tara
Flynn,Daphne Joy
French,Jennifer
Frese,Michelle
Hauser,Melissa Gerett
Huh,Sungun
Kilpatrick,Kelly
Kocak,Amy
Le,Jackie
Madenlian,Arpie
Mannino,Stephanie
Matier,Jacob
Nause,II II,Richard
Olson, Eric
Ortiz,Ronald
Perkins,Holly
Phillips,Carmen
Russell,Vance
Sallam,Julie
Saxena,Aditya
Stasiak,Andrew Erik
Taurozzi,John
Wang,Cheng-Chi
Weir,Lori
White,Tomas
Wu, Ting-Chen (Jennifer)

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Belite Bio Holdings Corp.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 12750 High Bluff Drive Ste. 475

City San Diego State CA Zip 92130

Mailing Address (if different from physical address) 12750 High Bluff Drive Ste. 475

City San Diego State California Zip 92130

Telephone (760) 809 7500 Website https://belitebio.com

Licensing Company Email licensing@belitebio.com

Section 2: Personal Information

First Ronald Middle N/A Last Ortiz

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

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

Mailing Address 12750 High Bluff Drive Ste. 475

City San Diego State California Zip 92130

Telephone (760) 809-7500 Email ronortiz@belitebio.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Arizona State University		8/2000 to 5/2002	
Address	**City**	**State**	**Zip**
300 E. Lemon Street	Tempe	Arizona	85287
Diploma/Degree obtained, if any			
MBA Supply Chain			

School Name		From - To (MM/YY – MM/YY)	
California State University Long Beach		12/1990-12/1992	
Address	**City**	**State**	**Zip**
1250 Bellflower Blvd	Long Beach	CA	90840
Diploma/Degree obtained, if any			
BS Chemistry			

School Name		From - To (MM/YY – MM/YY)	
El Camino High School		8/1992-6/1986	
Address	**City**	**State**	**Zip**
400 Rancho Del Oro Dr	Oceanside	Californi	92057
Diploma/Degree obtained, if any			
diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
8/2002 - present	[redacted]	Encinitas	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Belite Bio Holdings Corp.			12/2025	
Business Address		**City**	**State**	**Zip**
12750 High Bluff Drive Ste. 475		San Diego	CA	92130
Phone	**Title**		**Number of Employed Hours**	
(760) 809 7500	Senior Director, Head of Global Supply Chain			
Description of Duties				
see resume				

Business Name			From - To (MM/YY – MM/YY)	
Belite Bio Holdings			12/2025 to present	
Business Address		**City**	**State**	**Zip**
12750 High Bluff Drive Ste. 475		San Diego	CA	92130
Phone	**Title**		**Number of Employed Hours**	
(760) 809 7500	Sr. Director, Head of Global Supply Chain		see attached	
Description of Duties				
See attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Marinus Pharmaceuticals, Inc. (now Immedica Pharma)			2021-2025	
Business Address		**City**	**State**	**Zip**
Corporate Center, 5, 100 Matsonform Rd, Suite 500		Radnor	PA	19087
Phone	**Title**		**Number of Employed Hours**	
484-801-4670	VP, Global Supply Chain		see attached resume	
Description of Duties				
See attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Lafontaine de Borinquen LLC			4/2025-12/2025	
Business Address		**City**	**State**	**Zip**
		Encinitas	CA	
Phone	**Title**		**Number of Employed Hours**	
	owner		see resume	
Description of Duties				
see resume				

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

Continue on next page if additional space is needed.

[redacted]

RONALD S. ORTIZ

[redacted]

EXPERTISE & FOCUS:

- Diverse hi-tech industry new product development → QbD process from VOC to product TPP
- Extensive strategic supply chain design and improvement → Risk based methods across PSMD model
- Manufacturing process characterization statistical analysis → Predictive interrelationship modeling
- Broad business acumen and insight in design and execution → Portfolio management and S&OP planning
- Lean six sigma advanced principles & application MBB → Cost reduction and margin creation

PROFESSIONAL EXPERIENCE:

Belite Bio Holdings, CO, San Diego, CA **2025-Present**

Senior Director, Head of Global Supply Chain

Senior leadership position responsible for defining and executing the strategy for global commercial supply including vendor management from drug substance to finished drug product under a fully compliant and secure supply chain.

- Strategic Leadership: Develop and implement a scalable global supply chain strategy, including S&OP, demand planning, sourcing, and distribution, tailored for a growing, small-company environment.
- CMO Management: Oversee relationships with external manufacturing partners and suppliers, managing contract negotiations, performance metrics (KPIs), and quality standards.
- Operational Excellence: Drive efficiency and reduce costs across the supply chain, optimizing logistics and inventory levels to ensure continuity of supply.
- Compliance & Risk Mitigation: Ensure all logistics and manufacturing activities are compliant with international trade regulations and cGMP standards; develop contingency plans to mitigate supply risks.
- Cross-functional Collaboration: Partner with Commercial, Quality, Regulatory, and Finance teams to align supply chain operations with company goals and launch readiness.
- Systems Implementation: Select and optimize technology tools to improve supply chain visibility and data-driven decision-making.

Lafontaine de Borinquen, LLC, Encinitas, CA **4/2025-12/2025**

Owner

End-to-End Supply Chain Consulting with expertise in designing and building supply networks from API procurement through Drug Product manufacturing, packaging, labeling; to 3PL, Specialty Distribution and Pharmacy trade channels in a globalized commercial environment. I possess the right mix of Chemistry (B.S.), business acumen (MBA, Supply Chain) and Lean Six Sigma (Certified Master Black-Belt) to bring scalable growth from clinical trials to commercial launch.

Marinus Pharmaceuticals, Inc., Radnor, Pennsylvania (now Immedica Pharma, US) **2021-2025**

Vice President, Global Supply Chain **2024-2025**

Results-focused senior leadership position specializing in end-to-end Supply Chain Operations with 30+ years of progressively responsible experience. Adept at designing, building, and leading supply chain from clinical to global commercial scale including state licensure, product stewardship, trade channel negotiations, and DEA regulatory import/export compliance. Passionate hands-on leader skilled at building internal, external relationships, partnerships, and high performing teams: *Growth*

- Successfully transitioned US and global supply chain operations to new company entity via merger/acquisition.
- Demonstrated collaboration leadership with internal stakeholders for supply of global ZTALMY® via S&OP.
  - Led supply chain activities for US launch and guided partnership supply team for EU launch.
  - Forged global distribution pathways for China, MENA, Russia including both DEA and DSCSA compliance.
- Collaborated on future product/market strategies and indications for both the Oral and IV franchises.
  - Led the building of an IV supply chain for a hospital-based product launch (failed trial).
- Ensured the supply chain team remained proactive and agile while maintaining supply continuity.
- Grew emerging leaders within the supply chain with ever-scaling responsibilities.

1053

Ronald S. Ortiz, [redacted]

Executive Director, Supply Chain **2021**

- Led both Clinical and Commercial supply chains from API management, through DP manufacturing and segregation into commercial and investigation drug product packaging/labeling and distribution models.
- Led cross-functional team in RFP, selection and negotiation of trade channels (SP and SD) for product launch.
- Developed, implemented, and maintained policies, procedures, and material control systems to reduce costs, streamline procedures, and implement solutions.
- Ensured the availability of materials in the supply chain, as scheduled, and the maintenance of inventory at minimum acceptable levels.
- Was responsible for collaborating on sourcing and supplying raw materials, utilities, and outside services, as well as teaming on global procurement efforts.
- Coordinated with finance/accounting on matters involving inventory-carrying costs.
  - Reviewed and planned requirements for acceptable inventory.
- Assisted with the establishment and maintenance of the production control system within ERP implementation.
- Worked with customers in auditing customer inventory levels and with internal and external vendors to comply with inventory policies.
- Selected, hired, developed, and evaluated personnel to ensure the efficient operation of the function.

Nitto Avecia Pharma Services, Inc., Irvine, California **2018-2020**

Head of Commercial & Senior Director Operations Excellence

Executive level role responsible for commercial strategy and customer facing execution. Department head for Business Development, Marketing, Proposal Writing, Account Management/Inside Sales & Program Management Office:

Turn Around/Growth

- Overhaul of people, process, and systems to focus the organization on keeping core business while simultaneously building new client base.
  - Revamped AM/IS group to consistently achieve monthly targets.
    - Results: nearly $1M ahead of target for fiscal year 2020
  - Collaborated with President to overhaul Business Development both in personnel and in process and metrics to achieve corporate targets.
    - Results: proposal values increased by 92% and win rate increased from 20% to 46%
  - Co-creator of harmonized proposal writing and business development teams with parent company on specific market segment through ONE Avecia approach
  - Redefined customer relationships – moving from transactional to partnerships leading to greater repeat business.
  - Revised digital marketing campaigns and tradeshow materials to reflect current and future capabilities.
  - Upskilled PMO by introducing elements of Quality by Design (QbD) during formulation development to shorten timelines in a systematic approach.
    - Knowledge Space → Design Space → Normal Operating Range parameters vs "guess and test"

Pacira Pharmaceuticals, Inc., San Diego, California **2013-2018**

Head of Manufacturing Science, & Technology & Director Six Sigma

Two-pronged mission at Science Center Campus with a 4-person team: *Growth*

- Built basic business process capability in areas including supply chain, root cause investigation, and business planning.
  - Trained key team members in each focus area and building specific tools (playbook, scorecard, risk cube etc.) based on previous experience with AT Kearney purchasing chessboard, Hewlett-Packard TQRDCEB supplier scorecard and Raytheon supplier risk cube frameworks.
  - Led supply risk reduction for flagship product (as pilot for all future products) including Supply base profile analysis, procurement strategy definition, supplier performance monitoring and relationship development.
  - Led label redesign to include unique identifier for third party sales force application as part of strategic alliance.
  - Led package redesign for primary product incorporating new indication and supply base serialization.
  - Led successful planning and execution of supplier conference with flagship product suppliers leading to negotiated cost reductions of $900,000 the following year.
- Define critical process parameters and optimization methods for product portfolio to increase quality and/or reduce cost of manufacturing/development.
  - Introduced quality by design (QbD) program rollout for pipeline to shorten development cycle and lower cost.
  - Built project and program management capabilities through templates and best practices as standard work.
  - Successfully built statistical model to identify critical process parameter measurement error (true vs. reported by the system) that led to implementation of new measurement technology resolving an adverse quality trend.
  - Created additional multivariable linear regression models to identify critical process parameter interrelationships during the manufacturing/development process as the basis for DOEs and continued process verification (CPV).
  - Instituted more rigorous statistical process control (SPC) monitoring for quality control release criteria then trained key team members on the use of both CPV and SPC to perform more technically proficient root cause investigations.

Ronald S. Ortiz, [redacted]

Johnson & Johnson; Medical Devices (ASP), Irvine, California **2007-2013**

Chair for ASP Program Management Office (PMO) & Director, Business Process Optimization

Was franchise lead and Master Black-Belt (MBB) within Medical Device & Diagnostics Sector (MDD) that drove operational excellence and project management execution for better results in compliance, core and future growth: *Growth*

- Co-led creation of enterprise PMO focusing on franchise re-design to promote commercial process integration, systems infrastructure investment, and capability building in line with MDD sector changes leveraging cross-functional governance and project management best practice for enhanced, simpler and swifter business strategy & execution.
- Partnered with R&D to enhance New Product Development process to formally include QbD elements such as Quality Functional Deployment and quantitative FMEA that shorten the development cycle and increase product reliability at launch. – e.g. traveled to Tokyo to lead QFD with J&J Japan on new product which reached market in 2011 three months early and achieved all post commercialization metrics six months faster than any previous launch.
- Identified process parameters using advanced statistical analysis that impacted shelf life duration for biological indicator which led to manufacturing changes both on site and at one of the key suppliers in the growth and splitting process resolving the issue – wrote white paper to FDA explaining the analysis and subsequent remediation.
- Core team member on J&J sector level Lean manufacturing evaluation with A.T. Kearney and traveled to several European facilities to perform capability evaluations which were incorporated into a $1.2B cost savings proposal to corporate.
- Project management lead for remediation compliance plan that reported to Management Board and Corporate J&J weekly in response to FDA inspection results turning 9 of 10 red metrics green in 8 months' time.

Raytheon Space and Airborne Systems, El Segundo, California **2002-2007**

Senior Manager Mission Assurance (Quality Organization) **2006**

Was Performance Excellence advocate (program and product quality) for $4 Billion business unit focused on business process improvement ensuring procedures and protocols met Customers' mission success requirements: *Sustaining*

- Conducted Government Corrective Action Review (GCAR) with Response Team for VIIRS program.
- Successfully negotiated with both the prime (Raytheon) and subcontract (Northrop Grumman) teams on revised terms and conditions for ATFLIR program to avoid re-baseline schedule delay.
- Initiated early supplier involvement (ESI) with Space and Missile Command for JHPSSL program.
- Authored counterfeit electronic parts guideline and led requirements flow down overarching process improvement strategy to mitigate $80M/yr risk exposure.
- Led phase one deployment of an engineering quick turn supply chain procurement model for early phase feasibility space programs to shorten supply chain lead times 75%.
- Co-developed supplier risk cube methodology to quantify supply base risk based on elements of Raytheon's Supplier Rating System and Hewlett-Packard's TQRDCEB methodology then partnered with IT for applications development and deployment.

Manager II/III R6σ™ Lead, Supply Chain **2005**

Raytheon SAS supply chain management R6σ™ master black-belt – helped set direction and goals at the SCM leadership level for infusing Lean Six Sigma with integrated supply chain practices.

- Launched Supply Chain Transformation PMO as Control Account Manager (CAM) for initial $11M initiative during leadership change – was selected by site executives and A.T. Kearney during new VP search to drive first phase of multi-generational plan and achieved year one savings to target of $58M.
- Consulted routinely with Senior Vice President Operations on process discipline, organizational development, complexity reduction, strategic planning, tactical execution, and effective performance measures across four geographic sites totaling over 1000 Supply Chain employees.
- Worked well with all levels of the business to identify pain points and conducted business diagnostics that highlighted areas of opportunity, then led or assigned resources to execute improvements based upon greatest/swiftest impact (ROI, NPV, IRR, Payback Period, etc).
- Built and managed the Supply Chain Excellence PMO combining R6σ™, Supplier development, and knowledge management into a cohesive unit delivering expertise and solutions across the value stream – total of sixteen direct reports.
- Served as lead for supply chain process improvement strategies leveraging my team to drive cost improvement projects (CIPs) with annual targets greater than $15M.
- Coached and mentored green/black belt candidates and taught R6σ™ methodology to over 200 SAS employees.
- Core team member of PRISM (SAP) PMO serving as project management/earned value management system (EVMS) SME and supported the program through blueprint/realization strategy development across multiple geographic sites and two separate business units.

Ronald S. Ortiz, [redacted]

Manager I Supply Chain Business Systems Integration **2003**

- Was responsible for maintaining the business operating systems for Receiving, Inspection & Test, Warehousing, and Material Quality.
- Integrated Project Team Lead (IPTL) and CAM for $2.4M estimate at complete (EAC) project using EVMS to manage warehouse centralization and automation upgrade with SPI > 0.91, CPI > 0.66.
- Co-developed systems technology roadmap with IT for logistics operations in El Segundo – was later used as blueprint for multi-business unit logistics IT roadmap in preparation for PRISM (SAP) initiative.

Team Lead II, Warehouse Supervisor **2002**

- Supervised $2 million/year MRO/hazardous materials warehousing operation including procurement, receiving, stock-up, disbursement, and disposal (hazardous waste) – total of seven team members.
- Instituted Lean principles to reduce carrying costs of inventory and increase customer productivity.
- Improved communication with customer base to ensure satisfaction through better service by deploying feedback surveys and customer focus groups.
- Deployed new chemical management system utilizing 3rd Party procurement services to help lower operations costs by $1.2 million/year while maintaining high level of customer service.
- Led R6σ™ project to lean storeroom operations at our Mississippi manufacturing site resulting in $378,000 net present value savings.

Agilent Technologies, Inc., Rohnert Park, California **2001**

Supply Chain Analyst Summer Intern

- Rationalized miscellaneous purchased part commodity through migration of key parts to preferred suppliers.
- Negotiated smaller order quantities, shorter lead times and lower costs with these suppliers utilizing Economic Order Quantity (EOQ) theory, and Agilent's version of the HP TQRDCEB model for supplier evaluation.
- Created dynamic spreadsheet template for project progress tracking and managerial review.
- Solved data integrity problems within SAP environment and parallel legacy systems for selected purchased parts in support of enterprise software migration.
- Achieved $250,000/year savings through strategic sourcing efforts, identified $145,000 inadditional savings.

Schumacher: A Unit of Air Products and Chemicals, Carlsbad, California **1993 - 2000**

Senior Analytical Research Chemist

Was supervisor for Quality Assurance chemical analysis operations for both raw and finished products including coordination of Certificate of Analysis generation for a $60 million/year semiconductor supplier: *Learning*

- Identified, selected, and trained chemists and technicians on various SEMI standard laboratory operations, ISO-9001 procedures, and analytical equipment including extensive maintenance and troubleshooting within a Class 100 environment performing routine analysis at part per billion and part per trillion levels.
- Traveled to South Korea in support QA Laboratory build specifically overseeing the installation and qualification of a second MS-HR-ICPMS and trained staff on use and maintenance.
- Instituted and maintained SPC as an ASQ Certified Quality Engineer.
- Reduced chemical analysis cycle time 30% by increasing instrumental capacity and decreasing operational downtime 60% for critical piece of equipment.
- Managed installation and qualification project for $1 million magnetic sector high resolution inductively-coupled plasma mass spectrometer (MS-HR-ICPMS) which helped increase market share 10% postimplementation.
- Led employee incentive development team and proposed plan to senior management, which helped increase morale and overall throughput (survey feedback).
- Led waste-free strategy team, as a certified kaizen black-belt, which identified and reduced costs in largest product line by over $600,000/year by instituting a kanban system and redefining lotsizes.
- Received two awards for outstanding performance in meeting customer expectations during key supplier certification audits.

PUBLICATION/SPEAKING ENGAGEMENTS:

- Ortiz, Ronald S, Nitto Avecia Pharma Services: API to Clinic Within 4 Months, June 2019
- Ortiz, Ronald S, A New Pathway for Process Improvement, CXO Insights, Pharma Tech Outlook, December 2016
- Ortiz, Ronald S, Statistically Based Process/Product Characterization, Global Bioproduction Summit, December 2016
- Ortiz, Ronald S, Counterfeit Materials in Supply Chain, American Manufacturing Strategies Summit, November 2016

[redacted]

CERTIFICATION:

- Johnson & Johnson Master Black-Belt for ASP Franchise 2007
- Certified Raytheon Six Sigma Black-belt, 2004 & Master Black-Belt, 2005
- Air Products and Chemicals Certified Kaizen Black-Belt for Waste-Free Strategies, 2000
- Certified Quality Engineer through the American Society for Quality (ASQ), 1998 – 2001

EDUCATION: **Master of Business Administration, Supply Chain Management**
W.P. Carey School of Business, Arizona State University, Tempe, Arizona, 2002

Bachelor of Science, Chemistry
California State University Long Beach, Long Beach, California, 1992

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

_____ _____

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

I, Ronald Ortiz, **certify that as the designated representative for**

Belite Bio Holdings Corp.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ronald Ortiz

Print Name (First, Last)

Original Signature (electronic copies or stamps not accepted)

7/27/2026

Date

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

Ronald Ortiz

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

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

State of CALIF, ss. County of SAN DIEGO

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

Original Signature

7/27/2026

Date

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

Notary Public Signature

(Seal)

CALIFORNIA JURAT WITH AFFIANT STATEMENT

GOVERNMENT CODE § 8202

☒ See Attached Document (Notary to cross out lines 1–6 below)
☐ See Statement Below (Lines 1–6 to be completed only by document signer[s], *not* Notary)

1 _____

2 _____

3 _____

4 _____

5 _____

6 _____

Signature of Document Signer No. 1

Signature of Document Signer No. 2 (if any)

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

State of California
County of SAN DIEGO

Subscribed and sworn to (or affirmed) before me on this 27TH day of JULY, 2026
Date *Month* *Year*

by (1) RONALD ORTIZ

(and (2) _____),
Name(s) of Signer(s)

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

DAVID M. LYON
COMM. #2521680
NOTARY PUBLIC • CALIFORNIA
SAN DIEGO COUNTY
Commission Expires Jun 08, 2029

Signature _____
Signature of Notary Public

Seal
Place Notary Seal Above

OPTIONAL

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: _____ **Document Date:** _____

Number of Pages: ____ **Signer(s) Other Than Named Above:** _____

©2014 National Notary Association • www.NationalNotary.org • 1-800-US NOTARY (1-800-876-6827) Item #5910

6-K 1 tm2617120d1_6k.htm FORM 6-K

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15b-16 UNDER
THE SECURITIES EXCHANGE ACT OF 1934

For the month of June 2026

Commission File Number: 001-41359

Belite Bio, Inc

(Exact name of registrant as specified in its charter)

Not Applicable
(Translation of Registrant's name into English)

12750 High Bluff Drive Suite 475,
San Diego, CA 92130
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

On June 12, 2026, Belite Bio, Inc issued a press release entitled "Belite Bio Completes Rolling Submission of New Drug Application to U.S. Food and Drug Administration for Tinlarebant for the Treatment of Stargardt Disease Type 1." A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

This Report on Form 6-K and the related exhibit are incorporated by reference into all effective registration statements filed by the registrant under the Securities Act of 1933 and shall be a part thereof from the date on which this report is furnished, to the extent not superseded by documents or reports subsequently filed or furnished.

Exhibit No.	**Description of Exhibit**
99.1	Press Release

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Belite Bio, Inc

By: /s/ Yu-Hsin Lin
Name: Yu-Hsin Lin
Title: Chief Executive Officer and Chairman

Date: June 12, 2026

4L

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ■ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: A2A Integrated Logistics, Inc

Physical Address: 1830 Owen Dr. Ste 10-2

City: Fayetteville State: NC Zip: 28304

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 910-356-5500 Website: https://a2a-logistics.com/

Name of Designated Representative (DR): Dr. Rich White

Licensing Company Email: tbryant@a2a-logistics.com DR Email: rwhite@a2a-logistics.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	■ Controlled Substances	☐ Repacker
■ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

17 Aug 26
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Nivagen Pharmaceutical
Address: 3050 Fire Circle, Suite 100 City: Sacramento State: CA Zip: 95827

Name: PAI Pharma
Address: 1700 Perimeter Road City: Greenville State: NC Zip: 29605

Name: Meitheal Pharmaceuticals, Inc
Address: 8700 W BRYN MAWR AVE City: Chicago State: IL Zip: 60631

Name: Paragon Enterprises, Inc.
Address: 3300 Corporate Ave, Suite #114 City: Weston State: FL Zip: 33331

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: Anthony L Bryant
Business Name: A2A Integrated Logistics Inc
Business Address: 1830 Owen Dr. Ste 10-2
City: Fayetteville State: NC Zip: 28304
Telephone: 973-527-5299 Email: tbryant@a2a-logistics.com

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

A2A Integrated Logistics, Inc

Facility Name

Anthony L Bryant

Print Name of Authorized Person Submitting Application

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

17 Aug 26

Date

Board Use Only	Date Received: 8/25/26	Amount:

NABP ACCREDITED
DRUG DISTRIBUTOR

A2A Integrated Logistics Inc

located at

1830 Owen Dr, Ste 10-2 & Ste 10-3, Fayetteville, NC 28304

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

Wholesale Distributor and Third-Party Logistics Providers Reporting

About this Database (https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm423749.htm)
Back to Search Page (index.cfm)

Search Results for: "A2A Integrated Logistics"

Show all rowsCSV
Filter:

Facility Name	Facility Type	License Number	License State	License Expire	Reporting Year	Address	Facility Contact Name	Facility Contact Email
A2A Integrated Logistics Inc	WDD	179150	US-AK	06/30/2028	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	196177	US-AL	12/31/2026	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	W003503	US-AZ	10/31/2026	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	OSD7641	US-CA	09/01/2027	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	WHO.0008559	US-CO	10/31/2026	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	CSW.0005077	US-CT	06/30/2027	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	DM2100109	US-DC	07/31/2027	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	1232816	US-FL	04/30/2027	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	PHWH004968	US-GA	06/30/2027	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	004.005054	US-IL	12/31/2026	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	48002472A	US-IN	09/30/2028	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	4-114158	US-KS	06/30/2027	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com

Facility Name	Facility Type	License Number	License State	License Expire	Reporting Year	Address	Facility Contact Name	Facility Contact Email
A2A Integrated Logistics Inc	WDD	W04628	US-KY	09/30/2027	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	10117	US-LA	12/31/2026	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	5306006653	US-MI	05/04/2027	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	2021013882	US-MO	10/31/2027	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	CS-18323	US-MS	12/31/2026	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	502	US-NC	12/31/2026	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	Whol2721	US-ND	06/30/2027	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	1629	US-NE	07/01/2027	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	038684	US-NY	12/31/2026	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	0130000292	US-OH	06/30/2027	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	88-W-6835	US-OK	03/31/2027	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	0000516	US-OR	09/30/2027	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	19998	US-SC	06/30/2027	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	600-3470	US-SD	12/31/2026	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	0000006460	US-TN	01/31/2027	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	1003124	US-TX	11/30/2026	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	0219001961	US-VA	02/28/2027	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	PHWH.FX.61135508	US-WA	09/30/2026	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com
A2A Integrated Logistics Inc	WDD	3143	US-WI	05/31/2028	2026	Fayetteville NC	Anthony L Bryant	tbryant@a2a-logistic.com

NORTH CAROLINA
Department of the Secretary of State

CERTIFICATE OF AUTHORIZATION

I, ELAINE F. MARSHALL, Secretary of State of the State of North Carolina, do hereby certify that

A2A INTEGRATED LOGISTICS, INC.

a corporation organized under the laws of Florida was authorized to transact business in the State of North Carolina by issuance of a certificate of authority on the 8th day of March, 2016.

I FURTHER certify that the said corporation's certificate of authority is not suspended for failure to comply with the Revenue Act of the State of North Carolina; that the said corporation's certificate of authority is not revoked for failure to comply with the provisions of the North Carolina Business Corporation Act; that its most recent annual report required by G.S. 55-16-22 has been delivered to the Secretary of State; and that a certificate of withdrawal has not been issued in the name of the said corporation as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 6th day of October, 2025.

Elaine F. Marshall

Secretary of State

Scan to verify online.

Certification# 125083265-1 Reference# 23404361- Page: 1 of 1
Verify this certificate online at https://www.sosnc.gov/verification

North Carolina Department of Agriculture & Consumer Services

Food and Drug - Prescription Drug

Steve Troxler
Commissioner

Christina L. Waggett
Assistant Commissioner
for Consumer Protection

Anita MacMullan
Division Director

License Details for A2A Integrated Logistics Inc

Licensee Details

Firm Name: A2A Integrated Logistics Inc

License Type: Distributor

Mailing Address:

Physical Address: 1830 Owen Drive Ste 10-2 & 10-3, Fayetteville, NC 28304

License Status: Active – In good standing

License Number: 502

Current Issue Date: 12/22/2025

Discipline: No

Original Issue Date: 8/7/2017

License Expiration: 12/31/2026

Search URL: https://apps.ncagr.gov/AgRSysPortalV2/licensesearch/fdpd/376993

NCDA&CS
4400 Reedy Creek Road Raleigh, NC 27607-6465
1070 Mail Service Center, Raleigh, North Carolina 27699-1070
Main (984) 236-4820 : Fax: (919) 831-1323

2026

NOT TRANSFERABLE
STATUTE GS 81.106.119

North Carolina Department of Agriculture & Consumer Services
Steve Troxler, Commissioner
Food and Drug Protection Division

LICENSE/CERTIFICATE NO.
502

LICENSE/CERTIFICATE: **Distributor**
TYPE **PRESCRIPTION DRUG LICENSE**
Expiration Date **12/31/2026**

LICENSEE OR CERTIFICATOR
A2A Integrated Logistics Inc
1830 Owen Drive Ste 10-2 & 10-3
Fayetteville **NC** **28304**

LICENSED 2026 NORTH CAROLINA

Steven W. Troxler

STEVE TROXLER, COMMISSIONER

THIS LICENSE/CERTIFICATE MAY BE SUBJECT TO REVOCATION OR SUSPENSION AS PROVIDED BY LAW

Integrated Logistics
"UNCONDITIONAL SUPPORT"

1830 Owen Drive Suite 10-2
Fayetteville, NC 28304
Phone (D) (910) 356-5500
Phone (C) (973) 527-5299
Toll Free: 1-800-493-3637
(973) 787-9197 fax
Web: www.a2a-logistics.com

Date: August 11, 2026

SUBJECT: Current States of Prescription Pharmaceutical Licensing

To: Board of Pharmacy Official
From: Anthony L Bryant, CEO & President, A2A

Serial No #	LICENSE TYPE	STATE	LICENSE No.	ISSUE DATE	Expiration Date
1	Prescription Drug Enforcement Administration Distributor - Nonresident	WASHINGTON D.C.	RA0642822	27-May-26	30-June-27
2	Prescription Drug Wholesale Distributor- Resident	NORTH CAROLINA	502	19-Nov-20	31-Dec-26
3	Prescription Drug Wholesale Distributor - Nonresident	CALIFORNIA	OSD 7641	4-Sep-25	1-Sep-27
4	Prescription Drug Wholesale Distributor - Nonresident	LOUISIANA	10117	1-Jan-26	31-Dec-26
5	Prescription Drug Wholesale Distributor - Nonresident	OHIO	130000292	30-Nov-20	30-Jun-27
6	Prescription Drug Wholesale Distributor - Nonresident	VIRGINIA	219001961	22-Dec-20	28-Feb-27
7	Prescription Drug Wholesale Distributor - Nonresident	ARIZONA	W003503	12-Jan-21	31-Oct-26
8	Prescription Drug Wholesale Distributor - Nonresident	GEORGIA	PHWH004968	19-Jan-21	30-Jun-27
9	Prescription Drug Wholesale Distributor - Nonresident	WASHINGTON	PHWH.FX.61135508	13-Oct-25	30-Sep-26
10	Prescription Drug Wholesale Distributor - Nonresident	NEW YORK	38684	22-Jan-21	31-Dec-26
11	Prescription Drug Wholesale Distributor - Nonresident	TENNESSEE	6460	31-Jan-21	31-Jan-27
12	Prescription Drug Wholesale Distributor - Nonresident	TEXAS	1003124	30-Nov-20	30-Nov-26
13	Prescription Drug Wholesale Distributor - Nonresident	COLORADO	WHO.0008559	1-Nov-22	31-Oct-26
14	Prescription Drug Wholesale Distributor - Nonresident	OKLAHOMA	88-W-6835	3-Mar-22	31-Mar-27
15	Prescription Drug Wholesale Distributor - Nonresident	FLORIDA	232816	10-Sep-25	30-Apr-27
16	Prescription Drug Wholesale Distributor - Nonresident	SOUTH CAROLINA	19998	10-Jun-26	30-Jun-27
17	Prescription Drug Wholesale Distributor - Nonresident	MICHIGAN	5306006653	4-May-21	4-May-27
18	Prescription Drug Wholesale Distributor – Nonresident	MISSOURI	2021013882	6-May-21	31-Oct-27
19	Prescription Drug Wholesale Distributor – Nonresident (Virtual)	MISSISSIPPI	CS-18662	11-May-21	31-Dec-26
20	Prescription Drug Wholesale Distributor - Nonresident	ILLINOIS	4.005054	16-May-21	31-Dec-26
21	Prescription Drug Wholesale Distributor - Nonresident	KANSAS	4-114158	25-May-21	30-Jun-27
22	Prescription Drug Wholesale Distributor - Nonresident	NEBRASKA	1629	24-May-21	1-Jul-27
23	Prescription Drug Wholesale Distributor - Nonresident	WISCONSIN	3143-45	10-June-26	31-May-28
24	Prescription Drug Wholesale Distributor - Nonresident	ALASKA	179150	10-June-26	30-Jun-28
25	Prescription Drug Wholesale Distributor - Nonresident	INDIANA	48002472A	19-May-21	30-Sep-28

26	Prescription Drug Wholesale Distributor - Nonresident	OREGON	DDA-0000516	23-Jun-21	30-Sep-27
27	Prescription Drug Wholesale Distributor - Nonresident	WASHINGTON DC	DM2100109	1-Aug-22	31-Jul-27
28	Prescription Drug Wholesale Distributor - Nonresident	KENTUCKY	W04628	2-Nov-21	30-Sep-27
29	Prescription Drug Wholesale Distributor - Nonresident	ALABAMA	196177	15-Feb-22	31-Dec-26
30	Prescription Drug Wholesale Distributor - Nonresident	NORTH DAKOTA	Whol12721	17-Nov-21	30-Jun-27
31	Prescription Drug Wholesale Distributor - Nonresident	CONNECTICUT	CSW.0005077	10-May-22	30-Jun-27
32	Prescription Drug Wholesale Distributor - Nonresident	SOUTH DAKOTA	600-3470	17-Nov-25	31-Dec-26
33	Prescription Drug Wholesale Distributor - Nonresident	HAWAII	No State Requirement	No State Requirement	No State Requirement
34	Prescription Drug Wholesale Distributor - Nonresident	MASSACHUSETTS	No State Requirement	No State Requirement	No State Requirement
35	Prescription Drug Wholesale Distributor - Nonresident	MINNESOTA	PENDING	PENDING	PENDING
OTHER	National Association of Boards of Pharmacy (NABP)Verified Accredited Wholesale Distributor (VAWD)	National Accreditation	Cert# 106730 / eProfile#1525586	Awarded 13 APR 24	Current

IN WITNESS WHEREOF, I have executed my name as the company CEO & President.

Anthony L. Bryant
CEO & President
A2A Integrated Logistics

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	06-30-2027	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2N,3N,4	DISTRIBUTOR	05-27-2026

A2A INTEGRATED LOGISTICS INC
1830 OWEN DR STE 102
FAYETTEVILLE, NC 283043412

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	06-30-2027	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2N,3N,4	DISTRIBUTOR	05-27-2026

A2A INTEGRATED LOGISTICS INC
1830 OWEN DR STE 102
FAYETTEVILLE, NC 283043412

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	06-30-2027	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2N,3N,4	DISTRIBUTOR	05-27-2026

A2A INTEGRATED LOGISTICS INC
1830 OWEN DR STE 102
FAYETTEVILLE, NC 283043412

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
2012

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 7901353479

Application/License No. _____

A2A Integrated Logistics Inc (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1830 Owen Dr Ste 10-2, Fayetteville, NC 28304 (Address of Applicant/Principal), as PRINCIPAL, and Nationwide Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of OH (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1100 Locust Street, Department 2006, Des Moines, IA 50391 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 5, 2026 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 17th day of August, 2026.

APPLICANT/PRINCIPAL
A2A Integrated Logistics Inc

Authorized Representative
Anthony L Bryant, CEO

SURETY COMPANY
Nationwide Mutual Insurance Company

Surety Company's Representative
VALERIE ANN ABER, Attorney-in-fact
print name

SEAL

SIGNED and SEALED in the presence of:
Witness: Nadia Bryant

Witness: Leontii Popov

SIGNED and SEALED in the presence of:
Witness Hannah Coe

Witness Brian Jones

Countersigned by:
n/a
Nevada Resident Agent

Posted February 20, 2020

Bond Number: 7901353479

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS THAT

Nationwide Mutual Insurance Company, an Ohio corporation

hereinafter referred to severally as the "Company" and collectively as "the Companies" does hereby make, constitute and appoint:

VALERIE ANN ABER

each in their individual capacity, its true and lawful attorney-in-fact, with full power and authority to sign, seal, and execute on its behalf on the date thereof any and all: (i)bonds and undertakings, (ii) Proposal Bonds; (ii) Letters of Surety, (iv) Consent of Surety; and (v) other obligatory instruments of similar nature, in penalties not exceeding the sum of

Twenty Five Thousand and No/100 Dollars ($25,000.00)

and to bind the Company thereby, as fully and to the same extent as if such instruments were signed by the duly authorized officers of the Company; and all acts of said Attorney pursuant to the authority given are hereby ratified and confirmed.

This power of attorney is made and executed pursuant to and by authority of the following resolution duly adopted by the board of directors of the Company

"RESOLVED, that the president, or any vice president be, and each hereby is, authorized and empowered to appoint attorneys-in-fact of the Company, and to authorize them to execute and deliver on behalf of the Company any and all bonds, forms, applications, memorandums, undertakings, recognizances, transfers, contracts of indemnity, policies, contracts guaranteeing the fidelity of persons holding positions of public or private trust, and other writings obligatory in nature that the business of the Company may require, and to modify or revoke, with or without cause, any such appointment or authority, provided, however, that the authority granted hereby shall in no way limit the authority of other duly authorized agents to sign and countersign any of said documents on behalf of the Company."

"RESOLVED FURTHER, that such attorneys-in-fact shall have full power and authority to execute and deliver any and all such documents and to bind the Company subject to the terms and limitations of the power of attorney issued to them, and to affix the seal of the Company thereto; provided, however that said seal shall not be necessary for the validity of any such documents."

This power of attorney is signed and sealed under and by the following bylaws duly adopted by the board of directors of the Company.

Execution of Instruments. Any vice president, any assistant secretary or any assistant treasurer shall have the power and authority to sign or attest all approved documents, instruments, contracts, or other papers in connection with the operation of the business of the company in addition to the chairman of the board, the chief executive officer, president, treasurer or secretary; provided, however, the signature of any of them may be printed, engraved, or stamped on any approved document, contract, instrument, or other papers of the Company.

IN WITNESS WHEREOF, the Company has caused this instrument to be sealed and duly attested by the signature of its officer the 23rd day of October, 2025.

Antonio C. Albanese, **Vice President** of Nationwide Mutual Insurance Company

ACKNOWLEDGMENT

STATE OF OHIO COUNTY OF FRANKLIN: ss

On this 23rd day of October, 2025, before me came the above-named officer for the Company aforesaid, to me personally known to be the officer described in and who executed the preceding instrument, and he acknowledged the execution of the same, and being by me duly sworn, deposes and says, that he is the officer of the Company aforesaid, that the seal affixed hereto is the corporate seal of said Company, and the said corporate seal and his signature were duly affixed and subscribed to said instrument by the authority and direction of said Company.

Karen L. Kam
Notary Public, State of Ohio
No. 2018-RE-719796
Commission Expires July 7, 2028

Notary Public
My Commission Expires
July 7, 2028

CERTIFICATE

I, Lezlie F. Chimienti, Assistant Secretary of the Company, do hereby certify that the foregoing is a full, true and correct copy of the original power of attorney issued by the Company; that the resolution included therein is a true and correct transcript from the minutes of the meetings of the boards of directors and the same has not been revoked or amended in any manner, that said Antonio C. Albanese was on the date of the execution of the foregoing power of attorney the duly elected officer of the Company, and the corporate seal and his signature as officer were duly affixed and subscribed to the said instrument by the authority of said board of directors; and the foregoing power of attorney is still in full force and effect.

IN WITNESS WHEREOF, I have hereunto subscribed my name as Assistant Secretary, and affixed the corporate seal of said Company this 17th day of August, 2026.

Assistant Secretary

BDJ 1(10-25)00

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler A2A Integrated Logistics Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 1830 Owen Dr Ste 10-2

City Fayetteville State NC Zip 28304

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 910-356-5500 Website https://a2a-logistics.com/

Licensing Company Email tbryant@a2a-logistics.com

Section 2: Personal Information

First JOHN Middle RICHARD Last WHITE

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

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

Mailing Addres[redacted]

City Fayetteville State NC Zip[redacted]

Telephon[redacted] Email rwhite@a2a-logistics.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
UNC		1998-2002	
Address	City	State	Zip
301 Pharmacy Ln	Chapel Hill	NC	27599
Diploma/Degree obtained, if any			
Doctoral program			

School Name		From - To (MM/YY – MM/YY)	
UNC		1985-1987	
Address	City	State	Zip
301 Pharmacy Ln	Chapel Hill	NC	27599
Diploma/Degree obtained, if any			
BS degreee			

School Name		From - To (MM/YY – MM/YY)	
ECU		1982-1984	
Address	City	State	Zip
600 Moye Blvd	Greenville	NC	27834
Diploma/Degree obtained, if any			
undergraduate studies			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/26-Present	[redacted]	Fayetteville	NC	[redacted]
08/23 - 07/26		GREENSBORO	NC	
09/22 - 08/23		Browns Summit	NC	
02/19 - 09/22		GREENSBORO	NC	
From - To (MM/YY – MM/YY)	Address	City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
A2A Integrated Logistics, Inc			05/25-Present	
Business Address		**City**	**State**	**Zip**
1830 Owen Dr, Ste 10-2		Fayetteville	NC	28304
Phone	**Title**		**Number of Employed Hours**	
910-256-5500	Pharma-D		40+/Week	
Description of Duties				
Provide professional expertise related to contracts and related medication formularies. Ensures the company policies conforms to existing Medicare & Medicaid requirements for pharmaceuticals. Participates in compliance reviewing SOP's				

Business Name			From - To (MM/YY – MM/YY)	
UPSTREAM PHARMACY			10/19 - 09/24	
Business Address		**City**	**State**	**Zip**
1100 Revolution Mill Dr. Ste 10		Greensboro	NC	27405
Phone	**Title**		**Number of Employed Hours**	
336.285.7985	Director of Pharmacy		40+/Week	
Description of Duties				
Responsible for day to day operations in high volume pharmacy. *Worked directly with physician offices in 5 counties to* provide adherence packaging to patients to increase medication compliance,responsible for creating SOP for all aspects				

Business Name			From - To (MM/YY – MM/YY)	
TRIAD CARE			05/10 - 10/19	
Business Address		**City**	**State**	**Zip**
306 POMONA Dr. Suite L		GREENSBORO	NC	27407
Phone	**Title**		**Number of Employed Hours**	
(866) 885-7931	PHARMACIST-Founder and President.		40+/Week	
Description of Duties				
Responsible for medication therapy management services that improved patient adherence and health outcomes in chronic disease management. Conducted patient education sessions to promote understanding of medication regimes.				

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

_____ _____

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

I, Richard, White, **certify that as the designated representative for**

A2A Integrated Logistics, Inc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RW I am at least 21 years of age;
3. RW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

JOHN R WHITE

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/6/24

Date

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

JOHN R WHITE

Print Name (First, Last)

John R White

Original Signature (electronic, copies or stamps not accepted)

8/6/26

Date

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

State of North Carolina, ss. County of Guilford

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

John R White

Original Signature

8/6/26

Date

Subscribed and Sworn to before me this 6 day of August.

Novelle Rodriguez

Notary Public Signature

NOVELLE RODRIGUEZ
NOTARY
My Comm. Exp. 6/1/31
(Seal)
PUBLIC
GUILFORD COUNTY, N.C.

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

Personal History Application
Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site A2A Integrated Logistics Inc

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

Physical Address 1830 Owen Dr, Ste 10-2

City Fayetteville State NC Zip 28304

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 910-356-5500 Website https://a2a-logistics.com/

Licensing Company Email tbryant@a2a-logistics.com

Section 2: Personal Information

First Anthony Middle LaJuan Last Bryant

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

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

Mailing Addres[redacted]

City FAYETTEVILLE State NC Zi[redacted]

Telephor[redacted] Email tbryant@a2a-logistics.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Villanova University		10/2015-07/2017	
Address	City	State	Zip
800 Lancaster Ave	Villanova	PA	19085
Diploma/Degree obtained, if any			
Master Certificate Return On Investment			

School Name		From - To (MM/YY – MM/YY)	
Villanova University		05/2015-08/2016	
Address	City	State	Zip
800 Lancaster Ave	Villanova	PA	19085
Diploma/Degree obtained, if any			
Master Certificate Commercial Agile Contract Management			

School Name		From - To (MM/YY – MM/YY)	
Colorado State University.		01/2007-05/2011	
Address	City	State	Zip
1270 Campus Delivery.	Fort Collins	CO	80523
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Monterey Institute of International Studies		01/2001-05/2006	
Address	City	State	Zip
460 Pierce Street	Monterey	CA	93940
Diploma/Degree obtained, if any			
Master's			

School Name		From - To (MM/YY – MM/YY	
Fayetteville State University		12/1995-05/1998	
Address	City	State	Zip
1200 Murchison Road	Fayetteville	NC	28301
Diploma/Degree obtained, if any			
Bachelor's			

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/16 - PRESENT	[redacted]	FAYETTEVILLE	NC	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)
A2A INTEGERATED LOGISTICS			08/11 - PRESENT
Business Address	**City**	**State**	**Zip**
1830 OWEN DR STE 10-2	Fayetteville	NC	28304
Phone	**Title**		
910-356-5500	OWNER/CEO		
Description of Duties			
Responsible for establishing strategic direction, ensuring regulatory compliance, managing financial performance, overseeing operations, and fostering a culture of quality, integrity, and customer service.			

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

_____ _____

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

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

Anthony Bryant

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

ALB

Date

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

State of Nevada, ss. County of clark

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

Original Signature

08/27/2026

Date

Subscribed and Sworn to before me this 27th day of August 2026.

Notary Public Signature

David Amezola Barrera
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 25-0942-01
Expires February 12, 2029

Notarized remotely using audio-video communication technology via Proof.

(Seal)

A2A INTEGRATED LOGISTICS
UNCONDITIONAL SUPPORT

Date: 27 August 2026

To: Nevada Board of Pharmacy
From: Anthony L Bryant, CEO

Subject: **List of employees:**

Company Name: A2A Integrated Logistics Inc. **FEIN:** 45-2879955

1. **CEO & President:** Anthony L Bryant Jr.
2. **Customer Service & Order/ Transaction Mgr / Corp Administrator**: Carolina Batista
3. **PharmD/ VP Pharma Ops/CDR**: Dr. Rich White
4. **VP Business Development Pharmaceuticals & MEDSURGE Sales:** Isaiah Bryant
5. **Director - Allied Health Services Programs**: Johnny Davis
6. **CS-Ops/ Pharmacy Tech Lead**: Leo Popov

I have executed my name confirming this statement below.

Anthony L. Bryant CEO
A2A Integrated Logistics Inc

4M

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 01667	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10) ■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10)

Section 1: General Information

Facility Name: BioRidge Pharma, LLC

Physical Address: 325 Columbia Turnpike

City: Florham Park State: NJ Zip: 07932

Mailing Address (if different from physical address): 325 Columbia Turnpike, Suite 202

City: Florham Park State: NJ Zip: 07932

Telephone: (973) 564-8004 Website: bioridgepharma.com

Name of Designated Representative (DR): Robert Anderson

Licensing Company Email: bob.anderson@bioridgepharma.com DR Email: bob.anderson@bioridgepharma.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies ☐ Practitioners ☐ Hospitals ☐ Wholesalers ☐ Veterinarians ☐ Others:	☐ Dangerous Drugs ☐ Controlled Substances ☐ *Medical Products (medical devices, equipment, supplies, gases) ■ Others: Human Prescription Drugs	☐ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ■ Others: Virtual wholesaler

Section 2: ONLY COMPLETE THIS SECTION IF THE COMPANY IS WHOLESALING [a]Medical Products (medical devices, equipment, supplies and gases). Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

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

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 3 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

7/16/26
Date

Section 4: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Ardelyx Inc.
Address: 400 Fifth Avenue, Ste 210 City: Waltham State: MA Zip: 02451

Name: Veloxis
Address: 2000 Regency Parkway, Ste 500 City: Cary State: NC Zip: 27518

Name: Fresenius
Address: 920 Winter Street City: Waltham State: MA Zip: 02451

Name: Kaleo
Address: 10900 Nuckols Rd, #200 City: Seattle State: WA Zip: 98119

Section 5: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

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

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): Asembia Buyer LLC
Corporation/Organization Name: BioRidge Pharma
Mailing Address: 13413 Galleria Circle Building Q-300
City: Austin State: Texas Zip: 78738
Telephone: (516) 765-6520 Email: info@peakrockcapital.com
Contact Person Name: Robert Anderson

Section 7: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 8: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

BioRidge Pharma, LLC

Facility Name

Robert Anderson

Print Name of Authorized Person Submitting Application

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

7/16/26

Date

Board Use Only	Date Received: 7/23/26	Amount: 9,100 CK 1000007800

NABP ACCREDITED
DRUG DISTRIBUTOR

BioRidge Pharma LLC

located at

325 Columbia Tpke, Ste 111, Florham Park, NJ 07932

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

09/20/2024 - 09/19/2027
Period of Accreditation

CONFIDENTIAL/EXEMPT FROM FREEDOM OF INFORMATION ACT AND SIMILAR STATE REQUESTS

Ownership Information

Ownership & Leadership of Applicant Entity - NV License # WH01667

Applicant: **BioRidge Pharma, LLC**
325 Columbia Turnpike, Florham Park, NJ 07932

Ownership: The Applicant entity is wholly owned (100%) by Asembia Buyer, LLC, 13413 Galleria Circle Building Q-300, Austin, Texas 78738

Officers of BioRidge Pharma, LLC
Robert S Anderson - Chief Financial Officer
Thomas M Cohn - Chief Strategy Officer

Ownership & Leadership of Asembia Buyer LLC

Ownership: Asembia Buyer LLC, is wholly owned (100%) by Asembia Intermediate LLC

Officers of Asemiba Buyer LLC
Jung Woo Choi - Chief Financial Officer

Leadership of Asembia Intermediate LLC

Officers of Asemiba Intermediate LLC
Jung Woo Choi - Chief Financial Officer

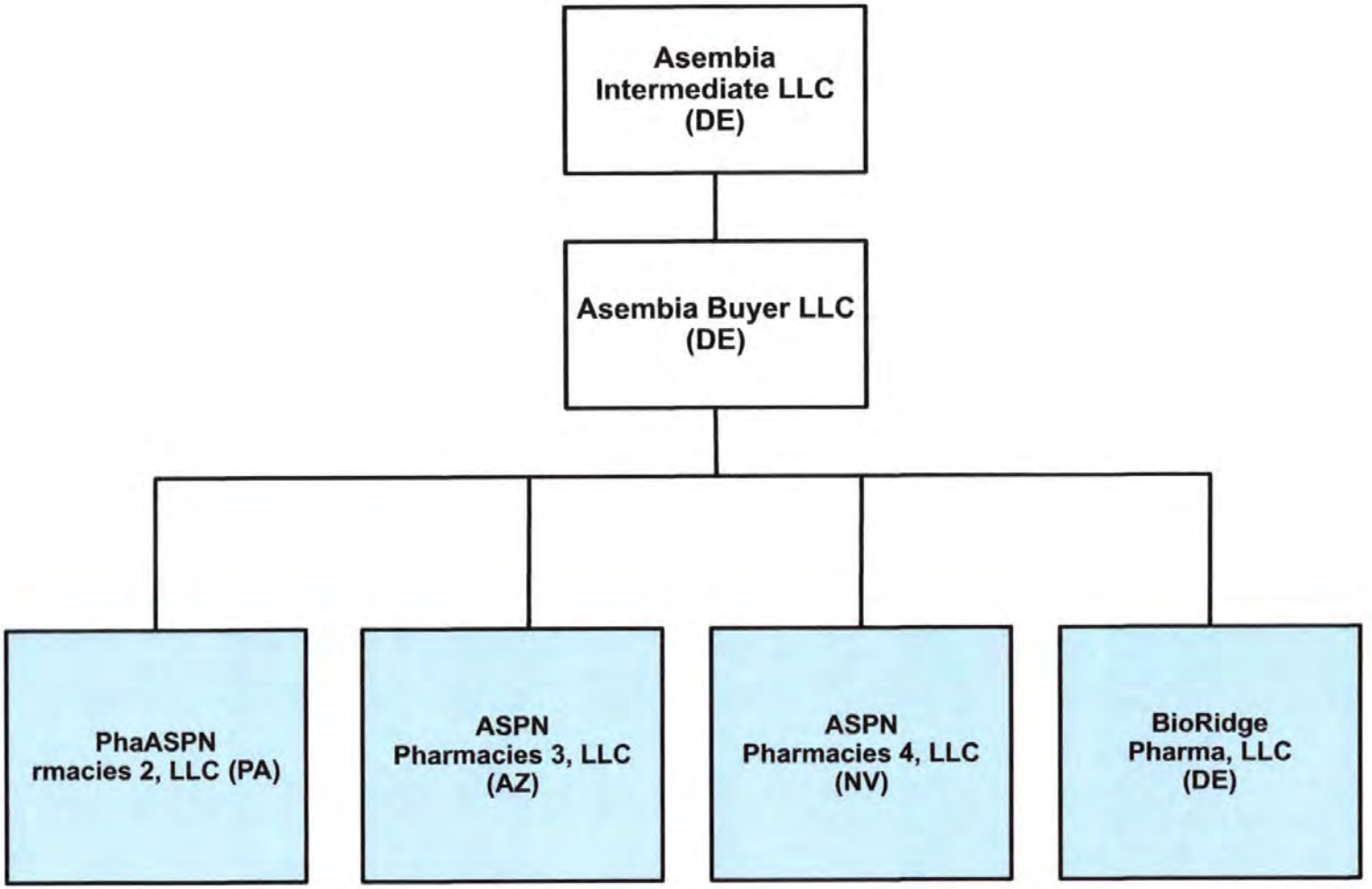
Please see the attached pre- and post-closing Corporate Organization chart for reference.

ASPN Pharmacies
Pre-Close Structure Chart



CONFIDENTIAL/EXEMPT FROM FREEDOM OF INFORMATION ACT AND SIMILAR STATE REQUESTS

ASPN Pharmacies
Post-Close Structure Chart



CONFIDENTIAL/EXEMPT FROM FREEDOM OF INFORMATION ACT AND SIMILAR STATE REQUESTS

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BIORIDGE PHARMA, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF AUGUST, A.D. 2026.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

4769731 8300

SR# 20263965296

Authentication: 204949994

Date: 08-26-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

Registration Number: 5003884 **Registered As:** Distributor

Information Recorded in the System as of 07/10/2026

Name: BIORIDGE PHARMA, LLC

New Jersey Department of Health

DBA:

Address: 325 COLUMBIA TPKE FLORHAM PARK, NJ 07932

Original Issue Date: 04/12/2010 **Expiration Date:** 01/31/2027

Current Issue Date: 10/15/2025

Disciplines: No

Permit Status: Active

NEW JERSEY DEPARTMENT OF HEALTH

CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0026045

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written noticeprior to the change of the address of such new location and the name and address of the individual to be in charge thereof.A fee of $20.00 shall accompanying such notification."

Registered as: ☐ Manufacturer ☑ Distributor which conducts business at the following locations:

Reg. No.:
5003884

BIORIDGE PHARMA, LLC
325 COLUMBIA TPKE
FLORHAM PARK, NJ 07932

ISSUED PURSUANT TO:
N.J.S.A. 24:6B
EXPIRES: January 31, 2027

Establishment Copy

intact INSURANCE surety

BOND
(License or Permit – Continuous)

Bond No. 800208327
Bond supercedes GCNA Bond#14112414
KNOW ALL MEN BY THESE PRESENTS:

THAT WE, BIORIDGE PHARMA, LLC
as Principal, and ATLANTIC SPECIALTY INSURANCE COMPANY, a corporation duly incorporated under the laws of the State of New York and authorized to do business in the State of New Jersey, as Surety, are held and firmly bound unto Nevada State Board of Pharmacy,
as Obligee, in the penal sum of One Hundred Thousand Dollars ($100,000) Dollars, for the payment of which we hereby bind ourselves, our heirs, executors and administrators, jointly and severally, firmly by these presents.

WHEREAS, the Principal has obtained or is about to obtain a license or permit for wholesale distributor or permit/permit holder

NOW, THEREFORE, THE CONDITIONS OF THIS OBLIGATION ARE SUCH, that if the Principal shall faithfully comply with all applicable laws, statutes, ordinances, rules or regulations, pertaining to the license or permit issued, then this obligation shall be null and void; otherwise to remain in full force and effect.

This bond shall become effective on June 30, 2026

PROVIDED, that regardless of the number of years this bond is in force, the Surety shall not be liable hereunder for a larger amount, in the aggregate, than the penal sum listed above.

PROVIDED FURTHER, that the Surety may terminate its liability hereunder as to future acts of the Principal at any time by giving thirty (30) days written notice of such termination to the Obligee.

SIGNED, SEALED AND DATED this 5th day of August, 2026.

BIORIDGE PHARMA, LLC
Principal

By: _____

ATLANTIC SPECIALTY INSURANCE COMPANY

By: _____
Anthony Melnick, Attorney-in-Fact

605 Highway 169 North, Suite 800
Plymouth, Minnesota, USA 55441
Web: intactspecialty.com/surety
E-mail: surety@intactinsurance.com

intact INSURANCE

Power of Attorney

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Anthony Melnick, Mark Horta, Matthew J. Swanick, William J. Paterno**, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2026.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2026, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON D. NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2030

_____
Notary Public

I, the undersigned, Assistant Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 5th day of August, 2026.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2030

_____
Nicole L. Pelletier, Assistant Secretary

Please direct bond verifications to surety@intact.insurance.com

[intact] specialty solutions
INSURANCE

Atlantic Specialty Insurance Company

Period Ended 12/31/2025

Dollars displayed in thousands

Admitted Assets	
Investments:	
Bonds	$ 2,885,455
Preferred Stocks	-
Common Stocks	934,259
Mortgage Loans	-
Real Estate	-
Contract Loans	-
Derivatives	-
Cash, Cash Equivalents & Short Term Investments	1,000,755
Other Investments	29,147
Total Cash & Investments	4,849,616
Premiums and Considerations Due	361,651
Reinsurance Recoverable	34,446
Receivable from Parent, Subsidiary or Affiliates	15,668
All Other Admitted Assets	93,238
Total Admitted Assets	5,354,619

Liabilities and Surplus	
Liabilities	
Loss Reserves	$ 1,403,740
Loss Adjustment Expense Reserves	330,086
Total Loss & LAE Reserves	1,733,826
Unearned Premium Reserve	866,171
Total Reinsurance Liabilities	51,082
Commissions, Other Expenses, and Taxes due	83,583
Derivatives	-
Payable to Parent, Subs or Affiliates	-
All Other Liabilities	1,357,715
Total Liabilities	4,092,377
Capital and Surplus	
Common Capital Stock	9,001
Preferred Capital Stock	-
Surplus Notes	-
Unassigned Surplus	682,458
Other including Gross Contributed	570,784
Capital & Surplus	1,262,242
Total Liabilities and C&S	5,354,619

State of Minnesota
County of Hennepin

I, Sarah A. Kolar, Secretary of Atlantic Specialty Insurance Company do hereby certify that the foregoing statement is a correct exhibit of the assets and liabilities of the said Company, on the 31st day of December, 2025, according to the best of my information, knowledge and belief.

Secretary

Subscribed and sworn to, before me, a Notary Public of the State of Minnesota on this 5th day of March, 2026.

Notary Public

KERRI RIECHERS
NOTARY PUBLIC
MINNESOTA
My Commission Expires Jan. 31, 2030

CONTINUATION CERTIFICATE

In consideration of premium charged, The Guarantee Company of North America does hereby confirm in force Bond No. 14112474 in the amount of $100,000.00 on behalf of BioRidge Pharma, LLC as Principal, in favor of Nevada State Board of Pharmacy for the period beginning June 30, 2025 and ending June 30, 2026 subject to all the terms and conditions of said bond;

PROVIDED that the liability of The Guarantee Company of North America shall not exceed in the aggregated the amount above written, whether the loss shall have occurred during the term of said bond or during any continuation or continuations thereof, or partly during said term and partly during any continuation or continuations thereof.

Signed and Sealed this 5th day of August, 2025

The Guarantee Company of North America

William J. Paterno, Attorney-in-Fact

WORLD

Phone: (732) 380-0900

Invoice # 388739	Page 1 of 1
Account Number	Date
BIORPHA-01	8/5/2025
BALANCE DUE ON	
8/5/2025	
AMOUNT PAID	Amount Due
	$3,000.00

BioRidge Pharma, LLC

BioRidge Pharma, LLC

Bob Anderson
325 Columbia Turnpike
Florham Park, NJ 07932

Visit our payment portal at:

https://worldinsurance.appliedpay.com/

Bond - Commercial PolicyNumber: 14112474 Effective: 6/30/2025 to 6/30/2026

Item #	Trans Eff Date	Due Date	Trans	Description	Amount
7061092	6/30/2025	8/5/2025	RENB	Renewal - L&P	$3,000.00
Bond Amount: $100,000 - Nevada State Board of Pharmacy					

Total Invoice Balance: **$3,000.00**

A convenience fee of 3.5% on credit card transactions or $4 on bank account transactions will be charged for electronic payments and these fees are non-refundable.

Make Checks Payable To:	Wire Payments:		Electronic Payments:
World Insurance Associates LLC LB#1807 PO Box 95000 Philadelphia, PA 19195-0001	Bank Name: Account Name: Bank Address: ABA (Wires): Account No.:	TD Bank, NA World Insurance Associates LLC 2 Wall Street, New York, NY 10005 031101266 4375185042	For ACH or Credit Card payment, please visit the following link: https://worldinsurance.appliedpay.com/

Important: Please include invoice number with all forms of payment.

NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: BioRidge Pharma, LLC

Pharmacy/Wholesaler License # (if applicable): WH01667

Physical Address: 325 Columbia Turnpike

City: Florham Park State: NJ Zip: 07932

Mailing Address (if different from physical address): 325 Columbia Turpike, Suite 202

City: Florham Park State: NJ Zip: 07932

Telephone: (973) 564-8004 Website: bioridgepharma.com

Licensing Company Email: bob.anderson@bioridgepharma.com

Section 2: Personal Information

First: Robert Middle: Last: Anderson

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

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

Mailing Address: 325 Columbia Turnpike, Suite 202

City: Florham Park State: NJ Zip: 07932

Telephone: (973) 564-8004 Email: bob.anderson@bioridgepharma.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Kansas State University		1980-1984	
Address	**City**	**State**	**Zip**
919 Mid-Campus Drive North	Manhattan	KS	66506
Diploma/Degree obtained, if any			
B.S.Finance			

School Name		From - To (MM/YY – MM/YY)	
Shawnee Mission High School		1978-1980	
Address	**City**	**State**	**Zip**
7401 Johnson Drive	Overland Park	KS	66202
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2010 to Present	[redacted]	Essex Fells	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

BIORIDGE PHARMA

325 Columbia Turnpike, Suite 111
Florham Park, New Jersey 07932
P: 973.564.8004 • F: 973.564.8010
BioRidgePharma.com

August 10, 2026

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

RE: BioRidge Pharma, LLC (WH01667)
Change of Ownership Deficiency Application Deficiency

The following statement is made in response to the change of ownership application deficiency for BioRidge Pharma, LLC (herein referred to as "License"), NV License No.WH01667.

DEFICIENCY: The Designated Representative did not list any experience in a pharmacy, or with a wholesaler in a capacity related to the dispensing and distribution of, and/or recordkeeping relating to, prescription drugs. The only experience listed is Head of Finance(section7), therefore they do not meet the requirements.

STATEMENT: I, Robert Anderson, have been a resolute employee of BioRidge Pharma LLC since 2010. In this capacity as Head of Finance, I have accumulated over 6,000 hours of experience directly relevant to the distribution, recordkeeping, and operation oversight of prescription drugs within the pharmaceutical industry.

BioRidge Pharma, LLC is a **virtual** wholesaler of prescription drugs. The facility does not store, ship or otherwise physically handle any prescription drug products.

My professional responsibilities encompass critical functions that ensure the integrity and safety of the pharmaceutical supply chain, including:

- **Regulatory Compliance & Audit:** He maintains direct oversight of financial compliance and audit functions, ensuring that all operations adhere strictly to complex pharmaceutical regulatory requirements.
- **Operational Oversight:** As a strategic leader within our specialty drug distribution organization, his role includes managing risk and driving operational efficiency essential for complaint drug distribution.
- **Financial Stewardship:** His management of financial reporting and planning is integral to the entire lifecycle of pharmaceutical product distribution and the rigorous recordkeeping required by law.

I do solemnly affirm that the above statement is true and accurate to the best of my knowledge.

Robert Anderson
Chief Financial Officer

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
BioRidge Pharma			2010 - Present	
Business Address		**City**	**State**	**Zip**
325 Columbia Turnpike, Suite 202		Florham Park	NJ	07932
Phone	**Title**		**Number of Employed Hours**	
(973) 564-8004	Chief Financial Officer		40 hrs per wk	
Description of Duties				
Head of Finance				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

7/16/22
Date

I, Robert Anderson, **certify that as the designated representative for**

_____,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Robert Anderson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/16/26

Date

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

Robert Anderson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/16/26

Date

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

State of New Jersey, ss. County of Morris

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

Original Signature

7/16/26

Date

Subscribed and Sworn to before me this 16 day of 2026.

Notary Public Signature

LISA M MASCARO NOTARY PUBLIC MY COMM. EXP. 11-13-2027 STATE OF NEW JERSEY

(Seal)

docusign

Certificate Of Completion

Envelope Id: DE46F76C-E60F-8E64-83A9-CCB3D0A31454
Subject: Complete with Docusign: Project Waystar_Closing Confirmation.docx
Source Envelope:
Document Pages: 3
Certificate Pages: 5
AutoNav: Enabled
EnvelopeId Stamping: Enabled
Time Zone: (UTC-08:00) Pacific Time (US & Canada)

Signatures: 2
Initials: 0

Status: Completed

Envelope Originator:
REAL Solutions Group Operations Team
808 SE Chkalov Dr
Ste 3-422
Vancouver, WA 98683
licensing@realsolutionsgroup.co
IP Address: 152.117.79.61

Record Tracking

Status: Original
6/22/2026 5:22:59 AM

Holder: REAL Solutions Group Operations Team
licensing@realsolutionsgroup.co

Location: DocuSign

Signer Events	Signature	Timestamp
Robert Anderson bob.anderson@asembia.com CFO Security Level: Email, Account Authentication (None)	DocuSigned by: Robert Anderson 3CA99C48CD4F47A... Signature Adoption: Pre-selected Style Using IP Address: 162.10.127.114	Sent: 6/22/2026 6:15:01 AM Viewed: 6/22/2026 6:15:56 AM Signed: 6/22/2026 6:16:02 AM
Electronic Record and Signature Disclosure: Accepted: 6/22/2026 6:15:56 AM ID: ca9f6ba6-ff73-4a10-99a8-7e3d6c35ed1e		
Spencer Moore moore@peakrockcapital.com Managing Director Peak Rock Capital Security Level: Email, Account Authentication (None)	Signed by: Spencer Moore 6B50EF5117444D7... Signature Adoption: Pre-selected Style Using IP Address: 98.6.114.106	Sent: 6/22/2026 6:15:00 AM Resent: 6/22/2026 2:11:05 PM Viewed: 6/22/2026 2:37:27 PM Signed: 6/22/2026 2:37:38 PM
Electronic Record and Signature Disclosure: Accepted: 6/22/2026 2:37:26 PM ID: 72108df7-6d3b-4a1a-87f8-9e597890387f		

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp
Christina Beyer christina.beyer@kirkland.com Security Level: Email, Account Authentication (None)	COPIED	Sent: 6/22/2026 6:15:02 AM
Electronic Record and Signature Disclosure: Not Offered via Docusign		

Carbon Copy Events	Status	Timestamp
Kiyong Song kiyong.song@kirkland.com Security Level: Email, Account Authentication (None) **Electronic Record and Signature Disclosure:** Not Offered via Docusign	COPIED	Sent: 6/22/2026 6:15:02 AM
Marisa Nardelli marisa.nardelli@kirkland.com Security Level: Email, Account Authentication (None) **Electronic Record and Signature Disclosure:** Not Offered via Docusign	COPIED	Sent: 6/22/2026 6:15:03 AM
Olivia Kaufmann olivia.kaufmann@kirkland.com Security Level: Email, Account Authentication (None) **Electronic Record and Signature Disclosure:** Not Offered via Docusign	COPIED	Sent: 6/22/2026 6:15:04 AM
Tyler Martin tyler.martin@kirkland.com Security Level: Email, Account Authentication (None) **Electronic Record and Signature Disclosure:** Not Offered via Docusign	COPIED	Sent: 6/22/2026 6:15:04 AM

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	6/22/2026 6:15:04 AM
Envelope Updated	Security Checked	6/22/2026 2:11:04 PM
Certified Delivered	Security Checked	6/22/2026 2:37:27 PM
Signing Complete	Security Checked	6/22/2026 2:37:38 PM
Completed	Security Checked	6/22/2026 2:37:38 PM

Payment Events	Status	Timestamps

Electronic Record and Signature Disclosure

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, REAL Solutions Group (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may access the documents for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a $0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact REAL Solutions Group:

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:
To contact us by email send messages to: help@realsolutionsgroup.co

To advise REAL Solutions Group of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at help@realsolutionsgroup.co and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

To request paper copies from REAL Solutions Group

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to help@realsolutionsgroup.co and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

To withdraw your consent with REAL Solutions Group

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;

ii. send us an email to help@realsolutionsgroup.co and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: https://support.docusign.com/guides/signer-guide-signing-system-requirements.

Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

By selecting the check-box next to 'I agree to use electronic records and signatures', you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify REAL Solutions Group as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you by REAL Solutions Group during the course of your relationship with REAL Solutions Group.

Docusign Envelope ID: DE46F76C-E60F-8E64-83A9-CCB3D0A31454

CONFIRMATION OF CLOSING

Reference is made to that certain Purchase Agreement, dated as of March 26, 2026 (the "Purchase Agreement"), by and among Asembia Buyer LLC, a Delaware limited liability company ("Buyer"), and Waystar Representative, LLC, a Delaware limited liability company ("Seller").

The undersigned hereby confirms as follows:

1. The transactions contemplated by the Purchase Agreement were consummated effective as of 12:01 a.m. Eastern Standard Time on June 23, 2026 (the "Closing Date");

2. The Company continues to hold ownership of the drug inventory and patient records prior to, as of the Closing Date and thereafter;

3. As of the Closing Date, the equity interests of Seller were assigned by Seller to Buyer;

4. Seller has received the purchase price in accordance with the Purchase Agreement; and

5. As of the Closing Date, Buyer owns 100% of the issued and outstanding equity interests in the Target and indirectly owns 100% of the issued and outstanding equity interests in the Company.

This Confirmation of Closing is subject in all respects to the terms and conditions of the Purchase Agreement. Nothing contained in this Confirmation of Closing shall be deemed to amend, limit, supersede, extinguish, operate as a waiver of, or otherwise modify any of the obligations (including, without limitation, indemnity obligations), agreements, covenants, representations or warranties of each party contained in the Purchase Agreement and/or any other agreements, certificates or documents referenced therein or delivered pursuant thereto (together with the Purchase Agreement, the "Transaction Agreements"). In the event of any conflict, contradiction or inconsistency between this Confirmation of Closing and the Transaction Agreements, the terms of the Transaction Agreements shall govern and control in all respects.

[*Signature page follows*]

Docusign Envelope ID: DE46F76C-E60F-8E64-83A9-CCB3D0A31454

SELLER:

Waystar Representative, LLC

By: DocuSigned by: Robert Anderson
3CA99C48CD4F47A...

Name: Robert Anderson

Title: Chief Financial Officer

Docusign Envelope ID: DE46F76C-E60F-8E64-83A9-CCB3D0A31454

BUYER:

Asembia Buyer LLC

Signed by:
By: Spencer Moore
6B50EF5117444D7...
Name: Spencer Moore
Title: Authorized Representative

BIORIDGE PHARMA

325 Columbia Turnpike, Suite 111
Florham Park, New Jersey 07932
P: 973.564.8004 • F: 973.564.8010
BioRidgePharma.com

Att7_List each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.

Robert Anderson
Edwin Rodriguez
Odetta Joseph
Daniel Massoud
Marlo Sanchez
Patrick Redmond
Plarent Sinamati

4N

NEVADA STATE BOARD OF PHARMACY

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

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Independent Pharmaceutical, LLC

Physical Address: 854 E Crescentville Road

City: West Chester State: OH Zip: 45246

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: 888-258-5036 Website: _____

Name of Designated Representative (DR): _____

Licensing Company Email: licensing.independentpharma@g DR Email: licensing.independentpharma@gmail.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: OTC Drugs	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Wholesale Distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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

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

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

6-4-2024
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: QUEST PHARMACEUTICALS INC
Address: 300 EAST CHESTNUT STREET City: AUBURN State: KY Zip: 42071

Name: PRIMED PHARMACEUTICALS
Address: 34 INDUSTRIAL WAY EAST City: EATONTOWN State: NJ Zip: 07724

Name: RICHIE PHARMACAL COMPANY INC
Address: 119 STATE STREET City: GLASGOW State: KY Zip: 42141

Name: MASTERS DRUG COMPANY INC
Address: 3600 PHARMA WAY City: MASON State: OH Zip: 45036

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

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

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Ohio
Parent Company (if any): K Mac Holdings, LLC & FTM Holdings
Corporation/Organization Name: Independent Pharmaceutical, LLC
Mailing Address: 854 E Crescentville Road
City: West Chester State: OH Zip: 45246
Telephone: 888-258-5036 Email: licensing.independentpharma@gmail.com
Contact Person Name: Daniel McCarthy

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✔	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Independent Pharmaceutical, LLC

Facility Name

Daniel Francis McCarthy

Print Name of Authorized Person Submitting Application

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

6-4-2026

Date

Board Use Only	Date Received: 8/25/26	Amount: $1000 CK# 3292

NABP ACCREDITED
DRUG DISTRIBUTOR

Independent Pharmaceutical LLC

located at

854 E Crescentville Rd, West Chester, OH 45246

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

03/18/2024 – 03/17/2027
Period of Accreditation

Officers
January 31, 2026

Dakota Halcomb President S.S. [redacted]
Office 854 E. Crescentville Road D.O
West Chester, Ohio 45246
Home [redacted]

Daniel McCarthy Vice-President / COO [redacted]
Office 854 E. Crescentville Road
West Chester, Ohio 45246
Home [redacted]

EIN 46-4007282
Incorporated October 13, 2013 Ohio

Independent Pharmaceutical LLC is a stand-alone limited liability company
and does not have any parent organization
or any subsidiary companies operating under it

UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF THE SECRETARY OF STATE

I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show INDEPENDENT PHARMACEUTICAL, LLC, an Ohio Limited Liability Company, Registration Number 2237240, was organized in the State of Ohio on October 11, 2013, is currently in FULL FORCE AND EFFECT upon the records of this office.

Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 6th day of January, A.D. 2026.

Ohio Secretary of State

Validation Number: 202600602742

Board of Pharmacy

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until June 30, 2027.

INDEPENDENT PHARMACEUTICAL

854 CRESCENTVILLE

WEST CHESTER, OH 45246

License Number: 012419900

License Type: Wholesaler - Category 3

Sub-Category: FS – Full Service

Expiration Date: June 30, 2027

Responsible Person – Print, sign, and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
DANIEL F. MCCARTHY	

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request in eLicense Ohio - elicense.ohio.gov.

Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	11-30-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	10-06-2025

INDEPENDENT PHARMACEUTICAL
VICE PRESIDENT
854 E. CRESCENTVILLE ROAD
WEST CHESTER, OH 452464843

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	11-30-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	10-06-2025

INDEPENDENT PHARMACEUTICAL
VICE PRESIDENT
854 E. CRESCENTVILLE ROAD
WEST CHESTER, OH 452464843

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 09/02/2026

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

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

PRODUCER CAI Insurance Agency, Inc. 2035 Reading Road Cincinnati OH 45202-1415	CONTACT NAME: Jerri Reich PHONE (A/C, No, Ext): (513) 221-1140 FAX (A/C, No): (513) 872-7519 E-MAIL ADDRESS: jreich@cai-insurance.com
INSURED Independent Pharmaceutical LLC 854 E Crescentville Rd West Chester OH 45246-4843	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Phenix Mutual — 23175 INSURER B : Motorists Insurance — 13331 INSURER C : Berkley National Insurance Co INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** 26-27 Master **REVISION NUMBER:**

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

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER			5000491077	04/14/2026	04/14/2027	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG [ ]	$ 1,000,000 $ 100,000 $ 5,000 $ 1,000,000 $ 2,000,000 $ Excluded $
A	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			5000491077	04/14/2026	04/14/2027	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) [ ]	$ 1,000,000 $ $ $ $
B	[X] UMBRELLA LIAB [X] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $			5000491383	04/14/2026	04/14/2027	EACH OCCURRENCE AGGREGATE [ ]	$ 1,000,000 $ $
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [ ] If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		5000491077	04/14/2026	04/14/2027	[ ] PER STATUTE [X] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	OH Stop Gap $ 500,000 $ 500,000 $ 500,000
C	Products Liability			LPL5064986-14	04/14/2026	04/14/2027	Overall Policy Aggregate Products Aggregate	$1,000,000 $1,000,000

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

CERTIFICATE HOLDER

Insured Use

CANCELLATION

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

AUTHORIZED REPRESENTATIVE

© 1988-2015 ACORD CORPORATION. All rights reserved.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 024287358

Application/License No. _____

Independent Pharmaceutical LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 854 E Crescentville Rd, West Chester, OH 45246 (Address of Applicant/Principal), as PRINCIPAL, and The Ohio Casualty Insurance Company (Surety Company), a corporation organized under the laws of the state of New Hampshire (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street, Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 07/01/2026 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 8th day of July, 20 26.

APPLICANT/PRINCIPAL
Independent Pharmaceutical LLC

Authorized Representative

SURETY COMPANY
Great American Insurance Company

Surety Company's Representative

Sara McNeill, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

POWER OF ATTORNEY

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: **8214290-983777**

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint,

Cynthia Cooper; Sara McNeill

all of the city of Phoenix state of AZ each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 1st day of July, 2025.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 1st day of July, 2025 before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2029
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 8th day of July, 2026.

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02/24

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

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

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

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Independent Pharmaceutical, LLC — MDEG License # (if applicable): N/A

Physical Address: 854 E Crescentville Road

City: West Chester — State: OH — Zip: 45246

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

City: _____ — State: _____ — Zip: _____

Telephone: 888-258-5036 — Website: https://www.independentpharmaceutical.com/

Licensing Company Email: Licensing.independentpharma@gmail.com

Section 2: Personal Information

First: Daniel — Middle: Francis — Last: McCarthy

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

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

Mailing Address: 854 E Crescentville Road

City: West Chester — State: OH — Zip: 45246

Telephone: [redacted] — Email: Licensing.independentpharma@gmail.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Institute of Medical and Dental Technology		8-85 - 5-86	
Address	City	State	Zip
11590 Century Blvd Ste 210	Cincinnati	OH	45246
Diploma/Degree obtained, if any			
Certified Emergency Technician			

School Name		From - To (MM/YY – MM/YY)	
Southern Ohio College		8-83 - 5-84	
Address	City	State	Zip
1101 Glendale Milford Rd	Cincinnati	OH	45237
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Colerain High School		9-82 - 5-83	
Address	City	State	Zip
8801 Cheviot Rd	Cincinnati	OH	45251
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12-96 - PRE	[redacted]	Cincinnati	OH	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

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

Business Name			From - To (MM/YY – MM/YY)	
Independent Pharmaceutical, LLC			09/2013 - Present	
Business Address		**City**	**State**	**Zip**
854 E Crescentville Road		West Chester	OH	45246
Phone	**Title**		**Number of Employed Hours**	
513-371-2933	VP/General Manager		24,960+ Hours	
Description of Duties				
Assisted in founding and launching business, overseeing operational, purchasing, sales and strategic functions				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

6-4-2024
Date

I, Daniel Francis McCarthy, **certify that as the MDEG Administrator for**

Independent Pharmaceutical, LLC,

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

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

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

Daniel McCarthy
Print Name (First, Last)

Daniel G McCarthy
Original Signature (electronic, copies or stamps not accepted)

6-4-2024
Date

Board Use Only	Date Received:



NEVADA STATE BOARD OF PHARMACY

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

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Independent Pharmaceutical, LLC

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 854 E Crescentville Road

City West Chester State OH Zip 45246

Mailing Address (if different from physical address) same as above

City State Zip

Telephone 888-258-5036 Website https://www.independentpharmaceutical.com/

Licensing Company Email licensing.independentpharma@gmail.com

Section 2: Personal Information

First Daniel Middle Francis Last McCarthy

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

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

Mailing Address 854 E Crescentville Road

City West Chester State OH Zip 45246

Telepho [redacted] Email licensing.independentpharma@gmail.com

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

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

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

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

School Name		From - To (MM/YY – MM/YY)	
Institute of Medical and Dental Technology		8-95 - 5-96	
Address	City	State	Zip
11590 Century Blvd Ste 210	Cincinnati	OH	45246
Diploma/Degree obtained, if any			
Certified Emergency Technician			

School Name		From - To (MM/YY – MM/YY)	
Southern Ohio College		8-83 - 5-84	
Address	City	State	Zip
1101 Glendale Milford Rd	Cincinnati	OH	45237
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Colerain High School		9-92 - 5-93	
Address	City	State	Zip
8801 Cheviot Rd	Cincinnati	OH	45251
Diploma/Degree obtained, if any			
High School Diploma			

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

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

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

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12-96 - PRESENT	[redacted]	Cincinnati	OH	[redacted]
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Independent Pharmaceutical, LLC			09/2013 - Present	
Business Address		City	State	Zip
854 E Crescentville Road		West Chester	OH	45246
Phone	Title		Number of Employed Hours	
513-371-2933	VP/General Manager		24,960+ Hours	
Description of Duties				
Assisted in founding and launching business, overseeing operational, purchasing, sales and strategic functions				

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

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

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

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

Continue on next page if additional space is needed.

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

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

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

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

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

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

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

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

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

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

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

6-4-2024
Date

I, Daniel Francis McCarthy, **certify that as the designated representative for**

Independent Pharmaceutical, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Daniel McCarthy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-4-2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Daniel McCarthy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-4-2024

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Hamilton

I, Daniel McCarthy, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6-4-2024

Date

Subscribed and Sworn to before me this 4th day of June 2024

Notary Public Signature

HAYLEY ABNEY
Notary Public
State of Ohio
My Comm. Expires
August 4, 2030

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Independent Pharmaceutical, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 854 E Crescentville Road

City West Chester State OH Zip 45246

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-258-5036 Website https://www.independentpharmaceutical.com

Licensing Company Email Licensing.independentpharma@gmail.com

Section 2: Personal Information

First Dakota Middle _____ Last Halcomb

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or IT[redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 854 E Crescentville Road

City West Chester State OH Zip 45246

Teleph[redacted] Email Kody@independentpharma.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Hamilton High School		08/09 - 05/13	
Address	City	State	Zip
1165 Eaton Ave	Hamilton	Ohio	45013
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]	City	State	[redacted]
10/24 - Present		West Chester	Ohio	
From - To (MM/YY – MM/YY)		City	State	
01/20 - 10/24		Hamilton	Ohio	
From - To (MM/YY – MM/YY)		City	State	
01/95 - 01/20		Hamilton	Ohio	
From - To (MM/YY – MM/YY)		City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Independent Pharmaceutical, LLC			12/25 - Present	
Business Address		**City**	**State**	**Zip**
854 E. Crescentville Rd		West Chester	Ohio	45246
Phone	**Title**			
(888) 258-5036	CEO			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
All New Concrete, LLC			03/23 - Present	
Business Address		**City**	**State**	**Zip**
1123 Millville Ave.		Hamilton	Ohio	45013
Phone	**Title**			
(513) 693-2333	Owner			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Diabetes Management Solutions, INC			02/23 - 04/25	
Business Address		**City**	**State**	**Zip**
955 S. Federal Hwy Suite 349		Fort Lauderdale	Florida	33316
Phone	**Title**			
(818) 612-6027	CEO			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Paramount Realty Group			07/23 - Present	
Business Address		**City**	**State**	**Zip**
510 Main St		Hamilton	Ohio	45013
Phone	**Title**			
(513) 302-4828	Administrator			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
E-Brands for Less, Inc			02/20 - 04/21	
Business Address		**City**	**State**	**Zip**
8445 Canoga Ave		Canoga Park	California	91304
Phone	**Title**			
(513) 302-4828	CEO			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
KND Trading			01/18 - Present
Business Address	**City**	**State**	**Zip**
850 S. Erie Blvd	Hamilton	Ohio	45013
Phone	**Title**		
(513) 302-4828	Owner		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
D&S Trading Corp.			01/18 - 03/22
Business Address	**City**	**State**	**Zip**
502 Main St.	Hamilton	Ohio	45013
Phone	**Title**		
(513) 302-4828	CEO		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	N/A	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

08/10/26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dakota Halcomb
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/10/26
Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Butler

I, Dakota Halcomb, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

08/10/26
Date

Subscribed and Sworn to before me this 10th day of August

Robyn Rosenow
Notary Public Signature



(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Independent Pharmaceutical, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 854 E Crescentville Road

City West Chester State OH Zip 45246

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-258-5036 Website https://www.independentpharmaceutical.com

Licensing Company Email Licensing.independentpharma@gmail.com

Section 2: Personal Information

First John Middle F Last Carter

Alias(es, nick[redacted]es, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City ~~Austin~~ Winberley State TX Zip [redacted]

Telephon[redacted]mail [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		NO
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		NO
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		NO

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		NO
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		NO

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Texas @ Austin			
Address	City	State	Zip
	Austin	TX	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
6/2020 - No	[redacted]	Austin	TX	[redacted]
2/2017 - No	[redacted]	Wimberley	TX	[redacted]
8/2016 - 11/20	[redacted]	Austin	TX	[redacted]
From - To (MM/YY – MM/YY)	[redacted]	City	State	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Simpler Trading			From - To (MM/YY – MM/YY): 2010 – 2026
Business Address: 8911 N. Capital of TX Hwy # 4200	City: Austin	State: TX	Zip: 78759
Phone: 512 266 8659	Title: Founder / Owner		
Description of Duties: CEO and content provider			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		NO
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		N/A
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		NO
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		NO
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		NO
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		NO
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		NO
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		NO
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		NO
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		NO

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below: N/A

Original Signature (electronic, copies or stamps not accepted)

07-15-2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Carter

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/15/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Travis

I, John Carter, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

07/15/2026

Date

Subscribed and Sworn to before me this 15th day of July.

Notary Public Signature

ANGELA D. GARZA
NOTARY PUBLIC
STATE OF TEXAS
EXPIRES 11-23-2028
ID # 4598359

(Seal)

Independent Pharmaceutical, LLC

Full name	Department
Allen, Kimberly A	Collections
Baudanza, John V	Sales
Bedinghaus, Crystal D	Accounting
Bradford, Temple L	Sales Manager
Bryant, Carlee J	Warehouse
Chapman, Jametria D	Sales
Chavies, Heather L	Sales
Crowley, Gina	Sales
Fishter, Stefanie L	Sales
Geisen, Josef	Returns
Haacke, Russell A	Sales
Halcomb, Dakota	CEO
Hutcheson, David C	Operations
Kanzlemar, Kerrie S	Warehouse
Klein, Lara F	Sales
Knauer, Kristen G	Sales
Knecht, Shirley J	Warehouse
Martin, Aimmie N	Sales
McCarthy, Daniel	VP
Murray, Christopher R	Sales
Nowlin, Avery G	Warehouse
Nowlin, Parker J	Warehouse
Poanco, Anayky M	Warehouse
Prather, Tina M	Sales
Rosenow, Robyn	Admin
Salyers, Adryona	Sales
Sapp, Deshawnda N	Sales
Smith, Dana	Sales
Smith, David A	Warehouse
Smith, Shawn T	Sales
Smith, Sierra	Admin
Tuley, Alexander	IT
Warren, Roger L	Sales
Wood, Annika	Warehouse

40

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10)

Section 1: General Information

Facility Name: Avive Solutions, Inc.

Physical Address: 185 Valley Drive

City: Brisbane State: CA Zip: 94005

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 1-800-489-4428 Website: www.avive.life

Name of Designated Representative (DR): Sanaz Mirkhani

Licensing Company Email: regulatory@avive.life DR Email: sanaz@avive.life

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies ☐ Practitioners ☐ Hospitals ☑ Wholesalers ☐ Veterinarians ☐ Others:	☐ Dangerous Drugs ☐ Controlled Substances ☑ [a]Medical Products (medical devices, equipment, supplies, gases) ☐ Others:	☑ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ☐ Others:

Section 2: ONLY COMPLETE THIS SECTION IF THE COMPANY IS WHOLESALING *Medical Products (medical devices, equipment, supplies and gases). Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 3 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 4: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attachment A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): N/A

Corporation/Organization Name: Avive Solutions, Inc.

Mailing Address: 185 Valley Drive

City: Brisbane State: CA Zip: 94005

Telephone: 1-800-489-4428 Email: regulatory@avive.life

Contact Person Name: Sanaz Mirkhani

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration See Attachment A 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment B		

Section 10: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment C	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment C		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment D	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment E		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - See Attachment C		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment F	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment G	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale [3]Medical Products (medical devices, equipment, supplies, gases). (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment H	✓	✓	✓	✓
• **If providing [3]Medical Products (medical devices, equipment, supplies, gases), supply a copy of proof of insurance (NAC 639.6957).** The Medical Products wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment I	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 9)				
• **Submit Fingerprints** following instructions found at: N/A https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20NRS%20639.500%20-%20Effective%2001.07.2026%20-%20Wholesaler%20-%20Post%20on%201.26.26.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. N/A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Avive Solutions, Inc.

Facility Name

Sanaz Mirkhani

Print Name of Authorized Person Submitting Application

Sanaz Mirkhani

Original signature of Authorized Person (copies or stamps not accepted)

07/07/2026

Date

Board Use Only	Date Received: 7/9/26	Amount: $1000 - CK 3358

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
AVIVE SOLUTIONS INC
185 Valley Drive
Brisbane, CA 94005
Registration Number: 3026007685
FEI Number*: 3026007685
Status: Active
Date Of Registration Status: 2026

Owner/Operator:
Avive Solutions Inc[6]
185 Valley Drive
Brisbane, CA 94005
Owner/Operator Number: 10086420[7]

Official Correspondent:
Rory Beyer
Avive Solutions, Inc
185 Valley Drive
Brisbane, CA 94005
Phone: 650-8677885

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

---

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10086420&OwnerOperatc
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10086420&OwnerOperatc

Page Last Updated: 07/20/2026

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsc | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of **Health & Human Services**

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10086420&OwnerOperatc
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10086420&OwnerOperatc

Attachment C

Corporation Information

Officers:

Rory Beyer
President

Sameer Jafri
CEO

Directors:

Rory Beyer
Sameer Jafri
Mike Perry
Ryan Drant
Jeff Trost
Darshana Zaveri
Rik Vandevenne

Shareholders (owners holding more than 1% ownership in the business):

Questa Capital
Percentage owned: 19.4%

River Cities Capital
Percentage owned: 9.8%

Catalyst Health Ventures
Percentage owned: 6.5%

Laerdal Million Lives Fund
Percentage owned: 8.3%

Rory Beyer
Percentage owned: 3.5%

Sameer Jafri
Percentage owned: 3.5%

No shareholder owns more than 10% of the business. As such, a Personal History Records application is not required.

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "AVIVE SOLUTIONS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF MARCH, A.D. 2026.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 203313318

Date: 03-11-26

6362917 8300

SR# 20261123104

You may verify this certificate online at corp.delaware.gov/authver.shtml

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	AVIVE SOLUTIONS, INC.
Entity No.:	4034268
Registration Date:	06/07/2017
Entity Type:	Stock Corporation - Out of State - Stock
Formed In:	DELAWARE
Status:	Active

The above referenced entity is active on the Secretary of State's records and is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of June 05, 2026.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 466613629

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

Avive Solutions, Inc.
185 Valley Drive
Brisbane , CA 94005

LICENSE NUMBER: 117175
EXPIRATION DATE: 10/26/2028

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Printed: 8/26/2026

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 8/25/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Marsh & McLennan Agency LLC
Marsh & McLennan Ins. Agency LLC
PO Box 85638
San Diego CA 92186
License#: 0H18131

CONTACT NAME: Leslie Wornath
PHONE (A/C, No, Ext): 858-875-3092 **FAX (A/C, No):**
E-MAIL ADDRESS: leslie.wornath@MarshMMA.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Columbia Casualty Company	31127
INSURER B : National Fire Insurance Compan	20478
INSURER C : Continental Insurance Company	35289
INSURER D : PROASSURANCE SPECIALTY INSURAN	
INSURER E :	
INSURER F :	

INSURED
Avive Solutions, Inc.
185 Valley Drive
Brisbane CA 94005
REVIVSOLUT

COVERAGES **CERTIFICATE NUMBER:** 838958669 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY [ ] PRO-JECT [X] LOC OTHER:			8033578637	8/24/2026	8/24/2027	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 1,000,000 $ 15,000 $ 1,000,000 $ 2,000,000 $ See limits below
C	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			8033578623	8/24/2026	8/24/2027	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
C	[X] UMBRELLA LIAB [X] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED [X] RETENTION $ 0			8033578606	8/24/2026	8/24/2027	EACH OCCURRENCE AGGREGATE	$ 10,000,000 $ 10,000,000
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N / A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $
A D	Products Comp OP/Professional Lia Excess Product Liability Claims Made			7092774557 EX26CA38009	8/24/2026 8/24/2026	8/24/2027 8/24/2027	Aggregate Aggregate Retroative Date	$5,000,000 $5,000,000 8/24/2024

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Cyber / Privacy Liability Coverage
CFC Underwriting Limited
Policy Number ESP0240950910
8/24/2026 to 8/24/2027
$5,000,000 Each Claim
$5,000,000 Aggregate
$10,000 Retention
Technology Errors & Omissions
See Attached...

CERTIFICATE HOLDER

Evidence of Coverage

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

© 1988-2015 ACORD CORPORATION. All rights reserved.

AGENCY CUSTOMER ID: REVIVSOLUT

LOC #:

ACORD®

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Marsh & McLennan Agency LLC	Avive Solutions, Inc. 185 Valley Drive Brisbane CA 94005
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: CERTIFICATE OF LIABILITY INSURANCE

$2,000,000 Aggregate
$10,000 Retention

Sexual Misconduct Liability Coverage
Gotham Insurance Company
8/24/2026 - 8/24/2027
Policy Number GL2026SAM00423
$1,000,000 Each Claim
$1,000,000 Aggregate
$15,000 Retention

Evidence of Coverage

© 2008 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY SUITE
206, RENO, NV 89521
(775) 850-1440 – (775) 850-1444 – FAX
pharmacy@pharmacy.nv.gov

PHARMACEUTICAL WHOLESALER CASH DEPOSIT IN LIEU OF BOND

Name of Applicant/Licensee: Avive Solutions, Inc.

Address: 185 Valley Drive

City: Brisbane State: CA Zip: 94005

The above named applicant/licensee (hereinafter referred to as Assignor), does hereby assign and set over to the Nevada State Board of Pharmacy (the Board) all right, title and interest of any kind whatsoever owned or held by Assignor in the cash sum of $25,000 which was delivered simultaneously with this form. Assignor provides the cash sum as security pursuant to NRS 639.515(2). This assignment is binding on Assignor, his/hers heirs, administrators, successors, and assigns, jointly or severally, and is conditioned that Assignor has made, or is about to make, application to the Board for a pharmaceutical wholesaler's license.

Assignor understands, acknowledges, and agrees that:

1. The Board is not authorized to refund the cash deposit until sixty days beyond the date upon which the Assignor ceases to be licensed by the Board.

2. The cash deposit will not draw interest and will be kept in a segregated fund within the Board's accounts.

3. The Board is authorized to remove from the cash deposit money to satisfy fines or costs assessed against the Assignor pursuant to NRS 639.515, and that if the Board removes any money from the cash deposit, Assignor shall replenish the cash deposit or shall deposit other security pursuant to NRS 639.515 sufficient to retain the total amount of the cash deposit or else Assignor's license may not be renewed.

Executed in Brisbane, CA on June 18, 2026.
City and State Date

Signature of Assignor's Authorized Representative

Sandeep Sayal
Print Name

CFO
Title

SECURITY FEATURES INCLUDE TRUE WATERMARK PAPER, HEAT SENSITIVE ICON AND FOIL HOLOGRAM.

Avive Solutions, Inc.
185 Valley Dr.
Brisbane, CA 94005

SVB, A Division of First Citizens Bank
90-4039/1211

3359 3359

7/7/2026

PAY TO THE ORDER OF STATE OF NEVADA

$ **25,000.00

Twenty five thousand and 00/100**********

DOLLARS

VALID VALID
VALID VALID
VALID VALID

MEMO

AUTHORIZED SIGNATURE

⑈003359⑈ ⑆[redacted]⑆ [redacted]⑈

Avive Solutions, Inc. 3359

Avive Solutions, Inc. 3359

1197

LMP100 M/P CHECK

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Avive Solutions, Inc. MDEG License # (if applicable) N/A

Physical Address 185 Valley Drive

City Brisbane State CA Zip 94005

Mailing Address (if different from physical address) same as physical address

City _____ State _____ Zip _____

Telephone 1-800-489-4428 Website www.avive.life

Licensing Company Email regulatory@avive.life

Section 2: Personal Information

First Sanaz Middle N/A Last Mirkhani

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City Menlo Park State CA Zip [redacted]

Telephone [redacted] Email sanaz@avive.life

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
San Jose State University		01/02 - 05/25	
Address	City	State	Zip
One Washington Square	San Jose State University	CA	95192
Diploma/Degree obtained, if any			
M.S. Industrial Engineering			

School Name		From - To (MM/YY – MM/YY)	
Amir Kabir University of Technology		01/97 - 05/01	
Address	City	~~State~~ Country	Zip
424 Hafex Ave.	Tehran	Iran	15875-4413
Diploma/Degree obtained, if any			
B.S. Textile Engineering			

School Name		From - To (MM/YY – MM/YY)	
Farasat High School		09/93 - 05/97	
Address	City	~~State~~ Country	Zip
No. 14, First Naz Alley, 4th Tangestan Street	Northern Pasdaran, Tehran	Iran	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/12 - present	[redacted]	Menlo Park	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Avive Solutions, Inc.			9/25 - Present	
Business Address		**City**	**State**	**Zip**
185 Valley Drive		Brisbane	CA	94005
Phone	**Title**		**Number of Employed Hours**	
1-800-489-4428	Head of Quality		~1,450	
Description of Duties				
Maintain company's quality system activities including document control, audits, product inspections, supplier evaluation, manufacturing controls, and complaint investigations				

Business Name			From - To (MM/YY – MM/YY)	
Mavericks Endo Inc.			8/23 - 6/25	
Business Address		**City**	**State**	**Zip**
4040 Campbell Ave		Menlo Park	CA	94025
Phone	**Title**		**Number of Employed Hours**	
650-326-2656	VP of Quality and Regulatory		~3,350	
Description of Duties				
Established and maintained the company's quality management system. Oversaw and managed supplier qualification, audits, and corrective actions, and regulatory compliance acitivties.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*: N/A

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Sanaz Mirkhani, **certify that as the MDEG Administrator for**

Avive Solutions, Inc.,

that I (initial that you have read and meet the following requirements):

1. S.M Have a high school diploma or its equivalent;
2. S.M Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. S.M Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. S.M Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sanaz Mirkhani
Print Name (First, Last)

Sanaz Mirkhani
Original Signature (electronic, copies or stamps not accepted)

07/07/2026
Date

Board Use Only	Date Received: 7/9/26

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Avive Solutions, Inc.
Pharmacy/Wholesaler License # (if applicable) N/A
Physical Address 185 Valley Drive
City Brisbane State CA Zip 94005
Mailing Address (if different from physical address) Same as physical address
City State Zip
Telephone 1-800-489-4428 Website www.avive.life
Licensing Company Email regulatory@avive.life

Section 2: Personal Information

First Sanaz Middle Last Mirkhani
Alias(es, nicknames, name changes, etc.)
Date of Birth [redacted] SSN or I[redacted] Sex ☐ M ☑ F ☐ X
Mailing Address [redacted]
City Menlo Park State CA Zip [redacted]
Telephon[redacted] Email sanaz@avive.life
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
San Jose State University		01/02 - 05/25	
Address	**City**	**State**	**Zip**
One Washington Square	San Jose	CA	95192
Diploma/Degree obtained, if any			
M.S. Industrial Engineering			

School Name		From - To (MM/YY – MM/YY)	
Amir Kabir University of Technology		01/97 - 05/01	
Address	**City**	**~~State~~ Country**	**Zip**
424 Hafex Ave.	Tehran	Iran	15875-4413
Diploma/Degree obtained, if any			
B.S. Textile Engineering			

School Name		From - To (MM/YY – MM/YY)	
Farasat High School		09/93 - 05/97	
Address	**City**	**~~State~~ Country**	**Zip**
No. 14, First Naz Alley, 4th Tangestan Street	Northern Pasdaran, Tehran	Iran	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/12 - present	[redacted]	Menlo Park	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Avive Solutions, Inc.			9/25 - Present	
Business Address		**City**	**State**	**Zip**
185 Valley Drive		Brisbane	CA	94005
Phone	**Title**		**Number of Employed Hours**	
1-800-489-4428	Head of Quality		~1,450	
Description of Duties				
Maintain company's quality system activities including document control, audits, product inspections, supplier evaluation, manufacturing controls, and complaint investigations				

Business Name			From - To (MM/YY – MM/YY)	
Mavericks Endo Inc.			8/23 - 6/25	
Business Address		**City**	**State**	**Zip**
4040 Campbell Ave		Menlo Park	CA	94025
Phone	**Title**		**Number of Employed Hours**	
650-326-2656	VP of Quality and Regulatory		~3,350	
Description of Duties				
Established and maintained the company's quality management system. Oversaw and managed supplier qualification, audits, and corrective actions, and regulatory compliance acitivties.				

Business Name			From - To (MM/YY – MM/YY)	
Tusker Medical Inc.			4/16 - 6/20	
Business Address		**City**	**State**	**Zip**
155 Jefferson Dr., Suite 200		Menlo Park	CA	94025
Phone	**Title**		**Number of Employed Hours**	
N/A - Acquired	Director of Quality		~7,650	
Description of Duties				
Implement the company's quality management system and supported company's compliance activities. Led FDA inspections and device approval activities				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Sanaz Mirkhani, **certify that as the designated representative for**

Avive Solutions, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. S M I am at least 21 years of age;
3. S M I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. S M I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. S M I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. S M I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. S M I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sanaz Mirkhani

Print Name (First, Last)

Sanaz Mirkhani

Original Signature (electronic, copies or stamps not accepted)

07/07/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sanaz Mirkhani

Print Name (First, Last)

Sanaz Mirkhani

Original Signature (electronic, copies or stamps not accepted)

07/07/2026

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of San Mateo

I, Sanaz Mirkhani, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Sanaz Mirkhani

Original Signature

7/07/26

Date

Subscribed and Sworn to before me this 7th day of July.

Notary Public Signature

Y. LI
COMM. #2539140
Notary Public - California
Alameda County
My Comm. Expires Nov. 16, 2029

(Seal)

Last Name	First Name	Worksite Location
Abad	Ryann Gabrielle	Brisbane, CA
Agosto	Priscilla	Brisbane, CA
Andrews	Margaret	Brisbane, CA
Asato	Kimberly	Brisbane, CA
Atanque Alavaren Jr	Nieto	Brisbane, CA
Batley	Annalisa	Brisbane, CA
Beyer	Rory	Brisbane, CA
Bosisio	Emily	Brisbane, CA
Brahana	Christopher	Brisbane, CA
Burnach	Heather	Brisbane, CA
Burris	Paul	Brisbane, CA
Canlas	Noel	Brisbane, CA
Cenadoza	Golda	Brisbane, CA
Cruz	Leonora	Brisbane, CA
Cruz Smiljanic	Christina	Brisbane, CA
Demarco	Jakob	Brisbane, CA
Dorsey	Daniel	Brisbane, CA
Duncan	Gwendolyn	Brisbane, CA
Eldridge	Jason	Brisbane, CA
Feneis	Greg	Brisbane, CA
Fitzgerald	Samantha	Brisbane, CA
Garza	Leonard	Brisbane, CA
Ginn	Joanna	Brisbane, CA
Gogineni	Swati	Brisbane, CA
Guevara	Oscar	Brisbane, CA
Herns	Julian	Brisbane, CA
Hilbert	Christian	Brisbane, CA
Jafri	Sameer	Brisbane, CA
Jain	Ananya	Brisbane, CA
Jarquin	Cheri	Brisbane, CA
Kantorczyk	Annette	Brisbane, CA
Kirk	MacKenzie	Brisbane, CA
Koenig	Jessica	Brisbane, CA
Leberknight	Randall	Brisbane, CA
Li	To Lam Dexter	Brisbane, CA
Li	Yan Ting	Brisbane, CA
Loo	Kevin	Brisbane, CA
Luo	Tony	Brisbane, CA
Lyons	Timothy	Brisbane, CA
Manzo	Valeria	Brisbane, CA
Martin	Andreea	Brisbane, CA
Mejia-Prieto	Milan	Brisbane, CA
Meza	Eric	Brisbane, CA

Mirkhani	Sanaz	Brisbane, CA
Moran	Ernesto	Brisbane, CA
Moreno	Ireri	Brisbane, CA
Motwani	Suneil	Brisbane, CA
Ordillo	Liza	Brisbane, CA
Overstreet	Tyler	Brisbane, CA
Patel	Dev	Brisbane, CA
Perry	Katilyn	Brisbane, CA
Pesin	Jimy	Brisbane, CA
Pikna	Sean	Brisbane, CA
Sayal	Sandeep	Brisbane, CA
Serrano	Leilani	Brisbane, CA
Sharma	Manasvi	Brisbane, CA
Sheikholeslami	Hamed	Brisbane, CA
Spielman-Sun	Maxwell	Brisbane, CA
Syrkin-Nikolau	Judith	Brisbane, CA
Tang	Arthur	Brisbane, CA
Thompson	Michael	Brisbane, CA
Torres	Jeena	Brisbane, CA
Ungco	Precious Charmane	Brisbane, CA
Urquiza	Marcos	Brisbane, CA
Walke	Anuja	Brisbane, CA
Walker	James	Brisbane, CA
Worku	Nahum	Brisbane, CA
Wu	Robert	Brisbane, CA
Yee	Andrew	Brisbane, CA
Yuan	Baochun	Brisbane, CA

4P

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10)

Section 1: General Information

Facility Name: Beckman Coulter, Inc.

Physical Address: 11800 South West 147 Ave.

City: Miami State: FL Zip: 33196

Mailing Address (if different from physical address): 250 S. Kraemer Blvd

City: Brea State: California Zip: 92821

Telephone: (305) 710-6581 Website: https://beckmancoulter.com

Name of Designated Representative (DR): Orlando Bascuas

Licensing Company Email: orlando.bascuas@beckman.com DR Email: orlando.bascuas@beckman.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies ☐ Practitioners ☐ Hospitals ☐ Wholesalers ☐ Veterinarians ☒ Others: Specialty Distributors	☐ Dangerous Drugs ☐ Controlled Substances ☒ *Medical Products (medical devices, equipment, supplies, gases) ☒ Others: Rx Device with no drug	☒ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ☐ Others:

Section 2: <u>ONLY COMPLETE THIS SECTION IF THE COMPANY IS WHOLESALING</u> [a]Medical Products (medical devices, equipment, supplies and gases). Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A <u>practicing</u> health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 3 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)
Christopher Sibley

6/22/2026
Date

Section 4: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): See Attached

Corporation/Organization Name: Beckman Coulter, Inc.

Mailing Address: 250 S. Kraemer Blvd

City: Brea State: California Zip: 92821

Telephone: (305) 710-6581 Email: orlando.bascuas@beckman.com

Contact Person Name: ORLANDO BASCUAS

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 10: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale [a]Medical Products (medical devices, equipment, supplies, gases). (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Products (medical devices, equipment, supplies, gases), supply a copy of proof of insurance (NAC 639.6957).** The Medical Products wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 9)				
• **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20NRS%20639.500%20-%20Effective%2001.07.2026%20-%20Wholesaler%20-%20Post%20on%201.26.26.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Beckman Coulter, Inc.
Facility Name

Christopher Sibley
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6/22/2026
Date

Board Use Only	Date Received: 9/4/26	Amount: $1000 ck 5981

Description of Operations

Beckman Coulter (Miami, FL Facility) is a medical device manufacturer and distributor of Class II medical devices. Beckman Coulter's products are distributed to hospitals for use in laboratories. Beckman Coulter's products do not contain a drug or drug component.

FDA FEI Number:
FDA Registration: 1061932

Distributor Information:
Beckman Coulter, Inc.
11800 South West 147 Ave., Miami, FL 33196
Contact: Orland Bascuas, (305) 710-6581

Beckman Coulter, Inc has 559 employees working on site during normal business hours.

Beckman Coulter's's hours of operation are 7:00 am – 6:00pm Monday through Friday and closed on Saturday and Sunday.

Beckman Coulter's's records are stored at their Miami, FL facility.

Beckman Coulter's's facility square footage is 500,000.

Company Information

Company Name: Beckman Coulter, Inc.
Address: 11800 South West 147 Ave.
City, State, Zip: Miami, FL 33196
Phone: (305) 710-6581
Website: https://www.beckmancoulter.com/
E-mail: orlando.bascuas@beckman.com

FEIN: 95-1040600
State of Formation: DE
Date Incorporated:07/11/1988
File Number:21661610

Ownership Information

Beckman Coulter, Inc is owned by the following companies.

Parent Company Name: DH Acquisition Holding GmbH – 49.039% ownership
Parent Company Address: Ernst-Leitz Strasse 17-37, Wetzlar, 35578, Germany
Parent Company FEIN: 98-0560219

Parent Company Name: Launchchange, Inc.– 43.504% ownership
Parent Company Address: Danaher Corporate, 200 Park Avenue, Suite 310, Orange Village, OH, 44122
Parent Company FEIN: 20-0888785

** Multiple other companies owning less than 2% that make up the remaining of the ownership. Please see below breakdown of information.

Tax ID	Address	Parent	% Parent Interest Held
98-0560219	Ernst-Leitz Strasse 17-37, Wetzlar, 35578, Germany	DH Acquisition Holding GmbH	49.039%
20-0888785	Danaher Corporate, 200 Park Avenue, Suite 310, Orange Village, OH, 44122, United States	Launchchange, Inc.	43.504%
59-1995548	2200 Pennsylvania Ave., NW, Suite 800W, Washington, DC, 20037, United States	Danaher Corporation	2.005%
22-2774330	Danaher Corporate, 200 Park Avenue, Suite 310, Orange Village, OH, 44122, United States	DH Holdings Corp.	1.878%
51-0401890	Danaher Corporate, 200 Park Avenue, Suite 310, Orange Village, OH, 44122, United States	KAIC Investment Company	1.369%
98-1468383	1B Heienhaff, L-1736 Senningerberg, Grand-Duchy of Luxembourg, Luxembourg	BCK Holdings S.à.r.l.	1.350%
98-0601426	Ernst-Leiz-Strasse 17-37, Wetzlar, 35578, Germany	HLHG GmbH	0.570%
04-2452202	Danaher Corporate, 200 Park Avenue, Suite 310, Orange Village, OH, 44122, United States	DH Holdings US II Inc.	0.147%
98-0601424	Ernst-Leitz Strasse 17-37, Wetzlar, 35578, Germany	DM HoldCo GmbH	0.110%
11-1541330	25 Harbor Park Drive, Port Washington, NY, 11050, United States	Pall Corporation	0.015%

91-6159635	2200 Pennsylvania Ave., NW, Suite 800W, Washington, DC, 20037, United States	FIC International Corporation	0.011%
84-2647840	2200 Pennsylvania Ave., NW, Suite 800W, Washington, DC, 20037, United States	Joslyn Holding Company, LLC	0.000%
			100%

Officers

Christopher Sibley, VP, Global Controller
Business Address: 250 S. Kraemer Blvd., Brea, CA 92821
Business Phone: 714-993-5321

Thomas Coffman, Senior VP, CFO
Business Address: 250 S. Kraemer Blvd., Brea, CA 92821
Business Phone: (714) 961-3056

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
BECKMAN COULTER, INC.
11800 SW 147TH AVE.
Miami, FL 33196
Registration Number: 1061932
FEI Number*: 3000203293
Status: Active
Date Of Registration Status: 2026

Owner/Operator:
BECKMAN COULTER, INC.[6]
250 S. Kraemer Blvd
Brea, CA 92821
Owner/Operator Number: 2050012[7]

Official Correspondent:
Ian Pilcher
1000 Lake Hazeltine Dr.
Bldg 322
Chaska, MN 55318
Phone: 443-3506459

Received 3/11/26 M.H

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

---

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2050012&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2050012&OwnerOperator

Page Last Updated: 07/13/2026

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsc | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of **Health & Human Services**

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2050012&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2050012&OwnerOperator

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BECKMAN COULTER, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTH DAY OF APRIL, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "BECKMAN COULTER, INC." WAS INCORPORATED ON THE ELEVENTH DAY OF JULY, A.D. 1988.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

2166160 8300

SR# 20261632201

Authentication: 203574960

Date: 04-07-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

From: Burnett, Rebecca <Rebecca.Burnett@myfloridalicense.com>
Sent: Wednesday, April 17, 2024 3:13 PM
To: Nichole Frame <Nichole.Frame@twolabs.com>
Subject: RE: Resident Facilities - FDA Approved Devices with no drugs or drug components

[External]

If the device is approved by the FDA, a permit is not required from our office. Florida does not have a medical device manufacturer application.

From: Nichole Frame <Nichole.Frame@twolabs.com>
Sent: Tuesday, April 16, 2024 1:42 PM
To: Burnett, Rebecca <Rebecca.Burnett@myfloridalicense.com>
Subject: Resident Facilities - FDA Approved Devices with no drugs or drug components

[NOTICE] This message comes from a system outside of DBPR. Please exercise caution when clicking on links and/or providing sensitive information. If you have concerns, please contact your Knowledge Champion or the DBPR Helpdesk.

Good day, Ms. Burnett,

I am just following up on the below communication to see if a Resident Manufacturer or Virtual Manufacturer of FDA-Approved Devices without Drugs or Drug Components is required to obtain a license in your state and, if a license is required, how the product type should be selected within the application.

Thank you for your time.

Respectfully,
Nichole Frame
Licensing Analyst
Commercial-Regulatory
TwoLabs PHARMA SERVICES
110 Riverbend Ave., Suite 100 | Powell, OH | 43065
mobile 304.270.7571 | **hours** M. – F. 7:30 AM – 4:00 PM
website | email | LinkedIn

The actual statutes state:
o) *Device manufacturer permit.–*

1. A **device manufacturer permit** is required for any person that engages in the manufacture, repackaging, or assembly of medical devices for human use in this state, except that a permit is **not required if:**

a. The person is engaged only in manufacturing, repackaging, or assembling a medical device pursuant to a practitioner's order for a specific patient; or

b. The person does not manufacture, repackage, or assemble any medical devices or components for such devices, except those devices or components which are exempt from registration pursuant to s. 499.015(8):

(8) Notwithstanding any requirements set forth in this part, **a manufacturer of medical devices that is registered with the federal Food and Drug Administration is exempt** from this section and s. 499.041(6) if:

(a) The manufacturer's medical devices are approved for marketing by, or listed with the federal Food and Drug Administration in accordance with federal law for commercial distribution; or

(b) The manufacturer subcontracts with a manufacturer of medical devices to manufacture components of such devices.

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 10/09/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. Philadelphia PA Office 100 North 18th Street 16th Floor Philadelphia PA 19103 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Beckman Coulter, Inc. 250 S. Kraemer Boulevard Brea CA 92821 USA	INSURER A: ACE American Insurance Company	22667
	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

Holder Identifier :

COVERAGES **CERTIFICATE NUMBER:** 570116134487 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			HDOG49363606	10/15/2025	11/01/2026	EACH OCCURRENCE	$2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$2,000,000
							MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$5,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$5,000,000
	OTHER:							
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	
	ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / HIRED AUTOS ONLY / SCHEDULED AUTOS / NON-OWNED AUTOS ONLY						BODILY INJURY (Per accident)	
							PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						PER STATUTE OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N / A (Mandatory in NH)						E.L. EACH ACCIDENT	
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	
							E.L. DISEASE-POLICY LIMIT	

Certificate No : 570116134487

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence of Insurance. RE: 2295 Progress Dr., Hebron, Kentucky 41048, 5355 W. 76th Street, Indianapolis, Indiana 46268, 5350 Lakeview Parkway South Dr., Indianapolis, Indiana 46268, 2040 Enterprise Blvd., West Sacramento, California 95691, 1000 Lake Hazeltine Dr., Chaska, Minnesota 55318, 250 S. Kraemer Blvd., Brea, California 92821, 2470 Faraday Ave., Carlsbad, California 92010, 11800 SW 147th Ave., Miami, Florida 33196, 7381 Empire Dr., Florence, Kentucky 41042, 740 West 83rd St., Hialeah, Florida 33014.

CERTIFICATE HOLDER

Beckman Coulter, Inc.
250 S. Kraemer Blvd.
Brea CA 92821 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc.

©1988-2015 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

VERIFICATION OF BOND IN FORCE
Form SB-3

Type of Bond: License/Permit Bond Pharmaceutical Wholesaler

Name of Principal: BECKMAN COULTER, INC.

Obligee: STATE OF NEVADA AND THE NEVADA STATE BOARD OF PHARMACY

Carrier: LIBERTY MUTUAL INSURANCE COMPANY

Bond Number: 019093581

Effective Date: June 17, 2024

Limit: $ 100,000.00

Premium: $ 300.00

This Bond is continuous with no definite expiration date. Sufficient Premium has been paid to satisfy the requirements of the Carrier for this bond to June 17, 2027.

LIBERTY MUTUAL INSURANCE COMPANY

By: _____

Patricia A. Rambo Attorney in Fact

Date: July 23, 2026

POWER OF ATTORNEY

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: **8213593 - 019022**

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Annmarie Breene, Babette Ward, Cathy H. Ho, Dana Donahue, Joanne C. Wagner, Kimberly G. Sherrod, Lori S. Shelton, Marisa Thielen, Patricia A. Rambo, Patricia Dorsaneo, Patrick Breene, Pedro Gonzalez, Jr., Sara Owens, Wayne G. McVaugh

all of the city of Philadelphia state of PA each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 3rd day of April, 2025.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 3rd day of April, 2025 before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2029
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 23rd day of July, 2026.

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02/24

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Beckman Coulter, Inc. MDEG License # (if applicable) Pending

Physical Address 11800 South West 147 Ave.

City Miami State FL Zip 33196

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (305) 710-6581 Website https://www.beckmancoulter.com/

Licensing Company Email orlando.bascuas@beckman.com

Section 2: Personal Information

First Orlando Middle _____ Last Bascuas

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Add [redacted]

City Brea State CA Zip [redacted]

Telephone (305) 710-6581 Email orlando.bascuas@beckman.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Barry University		See attached Resume	
Address	**City**	**State**	**Zip**
11300 NE 2nd Ave	Miami	FL	33168
Diploma/Degree obtained, if any			
BS			

School Name		From - To (MM/YY – MM/YY)	
Florida International University		See attached Resume	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Champagnat Catholic school		June 1984	
Address	**City**	**State**	**Zip**
2609 NW 7TH St	Miami	FL	33125
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/13/2006 current	[redacted]	Miami	FL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Beckman Coulter			03/09-Present
Business Address	**City**	**State**	**Zip**
see attached resume			
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			
see attached resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7-16-26
Date

I, Orlando Bascuas, **certify that as the MDEG Administrator for**

Beckman Coulter, Inc.,

that I (initial that you have read and meet the following requirements):

1. OB Have a high school diploma or its equivalent;
2. OB Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. OB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. OB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Orlando Bascuas

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-16-26

Date

Board Use Only	Date Received: 8141726

Orlando Bascuas

[redacted]

[redacted]

Proven Plant Manager/Continuous Improvement Leader with over 21 years of experience optimizing and managing multiple value streams. Responsibilities include 180M in production responsibilities with a yearly 9M payroll of 235 associates. Highly skilled in New product introduction, Production relocation, Danaher Business Systems (DBS), lean manufacturing and project management. Additional responsibilities include forecasting build rates, budgeting, Kaizen roadmap and FDA readiness. Present monthly Operations updates to business unit's Senior leadership (Presidents and Vice Presidents).

Director Production Operations/Plant Management

Dates Employed	**Oct 2021 -Present**
Employment Duration	**3 yrs 8 mos**
Location	**Miami, Florida, United States**

Responsible for managing Plant, overseeing 3 distinct Value Streams (Business Units) Hematology, Life Science and Microbiology representing 32 products. Responsibilities include managing all feeder lines, remanufacturing/repair, 3000 unique service spares and packaging of all service items and instruments. Coaching and mentoring management teams on DBS fundamentals to strive for continuous improvement.

Achievements:
Transformed plant by utilizing DBS Lean conversion tool to introduce 1 piece flow, reduce waste, Cycle time reduction, material at POU and inventory reduction. Delivered 24 kaizens a year to improve Safety, Quality, Delivery, inventory and productivity. Reduced Cycle time an average of 40% and Increased productivity by 30%. Lean conversion initiative has also achieved a 60% reduction in manufacturing floor space for efficient utilization.

Plant has been recognized by the DBS Office as Best in class in Danaher for Lean Conversion initiatives.
Introduced Score cards throughout all Product cells to improve Kaizen Sustainment and accountability.

Responsible for managing the Profit and Loss(P&L) of the site of 180M in volume and 9M on payroll. Continue to achieve yearly productivity improvements of 9% through the use of several DBS tools, (Lean Conversion, Standard Work).

Confidential - Company Proprietary

Project Manager (Core Team Leader) of site transfer (12 products) from Brea California to Miami, Florida. Responsibilities included identifying footprint needed at receiving site, identify Knowledge transfer team, create budget for transfer, create a VPM (Visual Project Management) to track all task and create collaboration culture to ensure a successful transfer. Project was completed on time and under budget (300K). Achievements during the transfer were reduced footprint by 40%, Cycle time reduction by 25% and 30% output increase per day, with no additional labor cost.

Facilitated several Shingijutsu Kaizen events across several Value streams that resulted in 50% productivity improvements and 30% VRK improvements.

Life Science Value Stream Senior Manager

Dates Employed	**Sep 2016 – Feb 2021**
Employment Duration	**5 yr 6 mos**
Location	**Miami, Florida, United States**

Responsible for overseeing 13 Life Science product lines (Flow Cytometry & Particle Characterization). Provide LEAN/DBS mentoring and support to all production leads to bring about necessary cultural change within company.

Achievements:

Managed a team of 60+ associates with yearly volume of $72M in an FDA regulated environment.

Member of due diligence team to vet out potential purchase of Xitogen in China to improve Flow Cytometry portfolio. Flew to Suzhou China with multi-functional team to ensure product would meet Business Unit needs.

After company was acquired, I led several kaizen events using several DBS tools to transform Xitogen (CytoFlex) into a world class manufacturing facility. Kaizens achieved 50% productivity improvements which led to a daily 50% increase output to meet increased customer demand.

Due to U.S Government Lab restrictions of not being able to purchase China made products, there was an initiative to duplicate all CytoFlex production lines in Miami, Florida. Identified cross functional team members for Knowledge and Quality system transfer. Traveled to China with transfer team and established Quality plan and design change plan for the project. Established training program with Suzhou leadership and technical operation support from Miami. Worked with LS VP of Finance on budget approval for project. Worked with outside counsel hired to establish minimum requirement for US made product. Products were successfully transferred and under budget.

Facilitated a Shin Kaizen event to improve OBQ (Out of Box Quality) in Flow Cytometry product line. Number one issue being reported in South Africa was loose hardware. We invited several field service engineers to participate in the kaizen which was instrumental in getting VOC. The event addressed all hardware related issues and released a system with all countermeasures implemented which shipped to South Africa to a remote location. Installation of the instrument went flawless with no issues reported.

Confidential - Company Proprietary

Initiatives in Inventory reduction: Reduce product lead time using DBS tools which resulted 100K inventory reduction. Facilitated kaizen and identified duplicate inventory at source factory and several distribution centers which led to 265K reduction. Worked with Several distribution centers across the globe and identified 700K of non-moving inventory which resulted in re-allocating material to source factory for consumption.

Improved Spares On-Time-Delivery performance from 62% to 98%. Improved Instrument On-Time-Delivery performance from 53% to 99%; success in role led to promotion.
Lead Shingijutsu Kaizen events resulting in 52% productivity improvement and 42% DPU reduction; Lead three winning teams

Project Manager (Core Team Leader) of site transfer (12 products) from Brea California to Miami, Florida. Responsibilities included identifying footprint needed at receiving site, identify Knowledge transfer team, create budget for transfer, create a VPM (Visual Project Management) to track all task and create collaboration culture to ensure a successful transfer. Project was completed on time and under budget (300K). Achievements during the transfer were reduced footprint by 40%, Cycle time reduction by 25% and 30% output increase per day, with no additional labor cost.

Managed a team of 70+ associates with monthly revenues of $3.2M in an FDA regulated environment.
Provided training and mentoring to team members which led to a reduction in process errors and productivity improvement.

Production Manger

Dates Employed	**Jan 2012 – Sep 2016**
Employment Duration	**4 yrs 9 mos**
Location	**Miami**

Responsible for overseeing 13 Life Science product lines (Flow Cytometry & Particle Characterization). Provide LEAN/DBS mentoring and support to all production leads to bring about necessary cultural change within company.

Managed a team of 60+ associates with yearly volume of $72M in an FDA regulated environment.

Member of due diligence team to vet out potential purchase of Xitogen in China to improve Flow Cytometry portfolio. Flew to Suzhou China with multi-functional team to ensure product would meet Business Unit needs.

Confidential © Company Proprietary

After company was acquired, I led several kaizen events using several DBS tools to transform Xitogen (CytoFlex) into a world class manufacturing facility. Kaizens achieved 50% productivity improvements which led to a daily 50% increase output to meet increased customer demand.

Due to U.S Government Lab restrictions of not being able to purchase China made products, there was an initiative to duplicate all CytoFlex production lines in Miami, Florida.

- Identified cross functional team members for Knowledge and Quality system transfer.
- Traveled to China with transfer team and established Quality plan and design change plan for the project.
- Established training program with Suzhou leadership and technical operation support from Miami.
- Worked with LS VP of Finance on budget approval for project.
- Worked with outside counsel hired to establish minimum requirement for US made product. Products were successfully transferred and under budget.
- Facilitated a Shin Kaizen event to improve OBQ (Out of Box Quality) in Flow Cytometry product line.
- Number one issue being reported in South Africa was loose hardware. We invited several field service engineers to participate in the kaizen which was instrumental in getting VOC.
- The event addressed all hardware related issues and released a system with all countermeasures implemented which shipped to South Africa to a remote location. Installation of the instrument went flawless with no issues reported.

Production Supervisor

Dates Employed	**Mar 2009 – Jan 2012**
Employment Duration	**2 yrs 10 mo**
Location	**Miami**

Responsible for overseeing 4 Life Science product lines (Particle Characterization Value Stream). Managed a team of 25 associates with a yearly volume of 12M in an ISO and GMP environment. Prioritized production schedules based on product introductions, equipment efficiency and materials supplies. Utilized problem solving techniques to implement both containment & root cause countermeasures. Act as Kaizen champion for team.

Achievements:
Core team member of Sorter Relocation project from Ft Collins Colorado to Miami, Fl. Responsible for creating knowledge transfer team for both Assembly and Testing process. Spend 2-months with Transfer team in Ft Collins ensuring tribal knowledge was captured and documented before site closure.

Confidential - Company Proprietary

Education

Barry University – Miami, FL – 1999

Bachelor of Science (BS), Information Technology

Florida International University – Miami, FL – 1989

Bachelor's degree, Electrical Engineering

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Beckman Coulter, Inc.

Pharmacy/Wholesaler License # (if applicable) Pending

Physical Address 11800 South West 147 Ave.

City Miami State FL Zip 33196

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (305) 710-6581 Website https://www.beckmancoulter.com/

Licensing Company Email orlando.bascuas@beckman.com

Section 2: Personal Information

First Orlando Middle _____ Last Bascuas

Alias(es, nicknames, name changes, etc.) _____

Date of Birt[redacted] SSN or ITIN[redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 11800 South West 147 Ave

City Miami State FL Zip 33196

Telephone (305) 710-6581 Email orlando.bascuas@beckman.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	Not Applicable	x

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Barry University		see attached resume	
Address	City	State	Zip
11300 NE 2nd Ave	Miami	FL	33168
Diploma/Degree obtained, if any			
BS			

School Name		From - To (MM/YY – MM/YY)	
Champagnat Catholic school		08/1980-06/1984	
Address	City	State	Zip
2609 NW 7TH St	Miami	Florida	33125
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/06-Present	[redacted]	Miami	FL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)	
Beckman Coulter		03/09-Present	
Business Address	City	State	Zip
see attached resume			
Phone	Title	Number of Employed Hours	
		see attached resume	
Description of Duties			
see attached resume			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7-16-26
Date

I, Orlando Bascuas, **certify that as the designated representative for**

Beckman Coulter, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. O.B I am at least 21 years of age;
3. O.B I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. O.B I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. O.B I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. O.B I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. O.B I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Orlando Bascuas

Print Name (First, Last)

O.B

Original Signature (electronic, copies or stamps not accepted)

7-16-26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Orlando Bascuas

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-16-26

Date

Please have this section completed in the presence of a Notary Public.

State of FL, ss. County of Miami-Dade

I, Eduardo Somarriva, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7-16-26

Date

Subscribed and Sworn to before me this 16th day of July 2026.

E. Somarriva

Notary Public Signature

Notary Public State of Florida
Eduardo Somarriva
My Commission HH 740303
Expires 11/13/2029

(Seal)

Employee List

Associate	Full Legal Name	Legal Name - First Name	Legal Name - Last Name
Jose Gonzalez-Trujillo	Jose A Gonzalez-Trujillo	Jose	Gonzalez-Trujillo
Rusela Lopez	Rusela Lopez	Rusela	Lopez
Sviatlana Kisialiova	Sviatlana Kisialiova	Sviatlana	Kisialiova
Daniel Portal	Daniel Portal	Daniel	Portal
Dayami Carballo	Dayami Carballo	Dayami	Carballo
Gretel Betancourt Rojas	Gretel Ivelise Betancourt Rojas	Gretel	Betancourt Rojas
Maria Hernandez De Leon	Maria Hernandez De Leon	Maria	Hernandez De Leon
Ursula Marquez	Ursula e Marquez	Ursula	Marquez
Marta Franco	Marta P. Franco	Marta	Franco
Robert Sias	Robert C Sias	Robert	Sias
Cesareo Frias	Cesareo Frias	Cesareo	Frias
Pedro Laserna	Pedro Laserna	Pedro	Laserna
Diego Suarez	Diego Suarez	Diego	Suarez
Marjorie Zilberberg	Marjorie Zilberberg	Marjorie	Zilberberg
Leonardo Hernandez	Leonardo Hernandez	Leonardo	Hernandez
Martin Johnson	Martin A Johnson	Martin	Johnson
Mario Aguiar Garcia	Mario G Aguiar Garcia	Mario	Aguiar Garcia
Phillip Hudson	Phillip J Hudson	Phillip	Hudson
Santos Castellanos	Santos P Castellanos	Santos	Castellanos
Rossmary Barnard	Rossmary Barnard	Rossmary	Barnard
Alvaro Amador	Alvaro J Amador	Alvaro	Amador
Basil Ellis	Basil A Ellis	Basil	Ellis
Milagros Parada	Milagros Parada	Milagros	Parada
Eric Hernandez	Eric Hernandez	Eric	Hernandez
Geneitha Wilder	Geneitha M Wilder	Geneitha	Wilder
Johon Mosquera	Johon A Mosquera	Johon	Mosquera
Francisco Crespo	Francisco E Crespo	Francisco	Crespo
Joseph Fermaint	Joseph Fermaint	Joseph	Fermaint
Silvia Coronado	Silvia R Coronado	Silvia	Coronado
William Jeudy	William Jeudy	William	Jeudy
Jose Ramos	Jose E Ramos	Jose	Ramos
Jose Gonzalez	Jose H Gonzalez	Jose	Gonzalez
Lorenzo Navarro	Lorenzo A Navarro	Lorenzo	Navarro
Aniana Villanueva	Aniana D Villanueva	Aniana	Villanueva
Roxana Munoz	Roxana Munoz	Roxana	Munoz
Josefina Navarro	Josefina Navarro	Josefina	Navarro
Randall Johnson	Randall G Johnson	Randall	Johnson
Vivian Carvajal	Vivian C Carvajal	Vivian	Carvajal
Mayrim Heredia	Mayrim Cruz Heredia	Mayrim	Cruz Heredia
Eric Cuervo	Eric Arys Cuervo	Eric	Cuervo
Marianela Hernandez	Marianela Hernandez	Marianela	Hernandez
Eduardo Rubio	Eduardo Rubio	Eduardo	Rubio
Jorge Adarraga	Jorge Adarraga	Jorge	Adarraga
Yirina Mayor	Yirina Mayor	Yirina	Mayor
Janine Santa Maria	Janine Santa Maria	Janine	Santa Maria
Israel Sosa	Israel Sosa	Israel	Sosa
Jose Romero	Jose M Romero	Jose	Romero
Manuel Aguilar	Manuel R Aguilar	Manuel	Aguilar
Yoel Lopez	Yoel O Lopez	Yoel	Lopez
Marta Casallas	Marta Casallas	Marta	Casallas
Francisco Rubio	Francisco Rubio	Francisco	Rubio

Confidential - Company Proprietary

Carlos Garcia	Carlos Garcia	Carlos	Garcia
Idilio Noviola	Idilio A Noviola	Idilio	Noviola
Raquel Cruz	Raquel Cruz	Raquel	Cruz
Miguel Atanes	Miguel A Atanes	Miguel	Atanes
Ermis Noviola	Ermis Noviola	Ermis	Noviola
Barbara Castillo	Barbara Castillo	Barbara	Castillo
Maidelyn Rocha	Maidelyn Rocha	Maidelyn	Rocha
Mirta Suarez	Mirta J Suarez	Mirta	Suarez
Ana Rodriguez	Ana M Rodriguez	Ana	Rodriguez
Mario Caraballo	Mario I Caraballo	Mario	Caraballo
Miguel Rangel	Miguel A Rangel	Miguel	Rangel
Warren Robleto	Warren R Robleto	Warren	Robleto
Miriela Diaz	Miriela Diaz	Miriela	Diaz
Margarita Busnadiego	Margarita A Busnadiego	Margarita	Busnadiego
Miriam Valeriano	Miriam E Valeriano	Miriam	Valeriano
Belinda De La Torre	Belinda De La Torre	Belinda	De La Torre
Jesus Hernandez	Jesus Hernandez	Jesus	Hernandez
Nelson Hernandez	Nelson Hernandez	Nelson	Hernandez
Lester Pineda	Lester R Pineda	Lester	Pineda
Abel Rodriguez	Abel A Rodriguez	Abel	Rodriguez
Pedro Landin	Pedro J Landin	Pedro	Landin
Armando Delgado	Armando B Delgado	Armando	Delgado
Jacqueline Moats	Jacqueline C Moats	Jacqueline	Moats
Israel Sosa	Israel Sosa Jr.	Israel	Sosa
Lourdes Aguirre	Lourdes Aguirre	Lourdes	Aguirre
Damaris De Pena (On Leave)	Damaris R De Pena	Damaris	De Pena
Rosina Gonzalez	Rosina Ines Gonzalez	Rosina	Gonzalez
Janet Hernandez Perez	Janet Hernandez Perez	Janet	Hernandez Perez
Norma Rivero	Norma B Rivero	Norma	Rivero
Hermes Gomez	Hermes J Gomez	Hermes	Gomez
Elvis Castrillon	Elvis Castrillon	Elvis	Castrillon
Carmen Diz	Carmen L Diz	Carmen	Diz
Juan Mier	Juan C Mier	Juan	Mier
Axel Vieyto	Axel Vieyto	Axel	Vieyto
Rolando Marante	Rolando Marante	Rolando	Marante
Frank Maria	Frank Maria	Frank	Maria
Daisy Urbina	Daisy Urbina	Daisy	Urbina
Luz Haro	Luz Haro	Luz	Haro
Maria Pena	Maria E Pena	Maria	Pena
Linnette Franco	Linnette J Franco	Linnette	Franco
Delia Rios	Delia P Rios	Delia	Rios
Jorge Montesino	Jorge L Montesino	Jorge	Montesino
Alicia Iglesias	Alicia Iglesias	Alicia	Iglesias
Gemilda Delgado	Gemilda Delgado	Gemilda	Delgado
Magaly Rubio	Magaly Rubio	Magaly	Rubio
Eduardo Arana	Eduardo A Arana	Eduardo	Arana
Javier Valdes	Javier A Valdes	Javier	Valdes
David Gomez	David F Gomez	David	Gomez
Aaron Almonte	Aaron Almonte	Aaron	Almonte
Flor Mendez	Flor M Mendez	Flor	Mendez
Reginald Dumas-Pierre	Reginald Dumas-Pierre	Reginald	Dumas-Pierre
Yeney Segui	Yeney Segui	Yeney	Segui
Liz Claro	Liz E Claro	Liz	Claro

Confidential - Company Proprietary

Adnaloy Macias	Adnaloy Macias	Adnaloy	Macias
Raul Gonzalez	Raul E Gonzalez	Raul	Gonzalez
Carmen Mieses (On Leave)	Carmen Luisa Mieses	Carmen	Mieses
Michael Moran	Michael P Moran	Michael	Moran
Sandra Rodriguez	Sandra Y Rodriguez	Sandra	Rodriguez
Jose Restrepo	Jose B Restrepo	Jose	Restrepo
Saul Cisneros	Saul Cisneros	Saul	Cisneros
Emma Ortiz Diaz	Emma Ortiz Diaz	Emma	Ortiz Diaz
Nelson Siza	Nelson Siza	Nelson	Siza
Daisy Mejia	Daisy A Mejia	Daisy	Mejia
Pedro Landin	Pedro J Landin	Pedro	Landin
Juana Pinto	Juana Rosa Pinto	Juana	Pinto
Jonathan Pena	Jonathan Pena	Jonathan	Pena
Omar Feliu	Omar Carlos Feliu	Omar	Feliu
Manuel Lores	Manuel Lores	Manuel	Lores
Diana Guerrero	Diana Guerrero	Diana	Guerrero
Fabiola Valdes	Fabiola Valdes	Fabiola	Valdes
Maria Tormo Baez	Maria M. Tormo Baez	Maria	Tormo Baez
Mari Juana Cabrera	Mari Juana Cabrera	Mari Juana	Cabrera
Andy Alfonso	Andy Alfonso	Andy	Alfonso
David Perez	David Lazaro Perez	David	Perez
Mayra Castillo	Mayra Alejandra Castillo	Mayra	Castillo
Francisco Carrandi	Francisco Ivan Carrandi	Francisco	Carrandi
Lietter Cabrera Figueredo	Lietter Cabrera Figueredo	Lietter	Cabrera Figueredo
Katia Pizarro	Katia Pizarro	Katia	Pizarro
Mayelin Hernandez	Mayelin Hernandez	Mayelin	Hernandez
Lina Rivera	Lina Rivera	Lina	Rivera
Yareily Rocha	Yareily Rocha	Yareily	Rocha
Kenneth Guyton	Kenneth Guyton	Kenneth	Guyton
Shandreka Willard	Shandreka Willard	Shandreka	Willard
Adriana Osorno	Adriana Osorno	Adriana	Osorno
Suanis Guevara	Suanis Guevara	Suanis	Guevara
Vilma Soraya Gonzalez	Vilma Gonzalez	Vilma	Gonzalez
Oscar Duran	Oscar Duran	Oscar	Duran
Eugenio Schiavello	Eugenio Schiavello	Eugenio	Schiavello
Karla Molina Frontado	Karla Molina Frontado	Karla	Molina Frontado
Viviam Lopez	Viviam Lopez	Viviam	Lopez
Iranitza Nolaya	Iranitza Nolaya	Iranitza	Nolaya
Maria Gonzalez	Maria Gonzalez	Maria	Gonzalez
Elizabeth Quintero Buitrago	Elizabeth Quintero Buitrago	Elizabeth	Quintero Buitrago
Wynton Jones	Wynton Jones	Wynton	Jones
EFRAIN ARANDA	EFRAIN ARANDA	EFRAIN	ARANDA
Antony Vasquez Rosales	Antony Vasquez Rosales	Antony	Vasquez Rosales
Luz Angela Naranjo	Luz Angela Naranjo	Luz Angela	Naranjo
Marcia Rodriguez Perez	Marcia Rodriguez Perez	Marcia	Rodriguez Perez
Roberto Carhuayo	Roberto Carhuayo	Roberto	Carhuayo
Francisco Paulino	Francisco Paulino	Francisco	Paulino
Brandon Lopez	Brandon Lopez	Brandon	Lopez
Humberto Silva	Humberto Silva	Humberto	Silva
Ivette Garcia Cancio	Ivette Garcia Cancio	Ivette	Garcia Cancio

Confidential - Company Proprietary

4Q

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10) ■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10)

Section 1: General Information

Facility Name: bioFire Diagnostics, LLC

Physical Address: 515 Colorow Drive

City: Salt Lake City State: UT Zip: 84108

Mailing Address (if different from physical address): Attn; Sandra Perreand c/o Mary Vomund, 595 Anglum Road

City: Hazelwood State: MO Zip: 63042

Telephone: 801-736-6354 Website: www.biomerieux.com

Name of Designated Representative (DR): Tyler Jacob Farrell

Licensing Company Email: statelicensing@biomerieux.com DR Email: statelicensing@biomerieux.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies ☐ Practitioners ■ Hospitals ■ Wholesalers ☐ Veterinarians ☐ Others:	☐ Dangerous Drugs ☐ Controlled Substances ■ *Medical Products (medical devices, equipment, supplies, gases) in vitro diagnostic tests, reagents and equipment ☐ Others:	■ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ■ Others: Medical Devices

Section 2: ONLY COMPLETE THIS SECTION IF THE COMPANY IS WHOLESALING [a]Medical Products (medical devices, equipment, supplies and gases). Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 3 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

07JUL26
Date

Section 4: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Louisville IDC UPS Healthcare
Address: 2260 Outer Loop City: Louisville State: KY Zip: 40219

Name: Mira Loma IDC UPS Healthcare
Address: 11991 Landon Dr City: Mira Loma State: CA Zip: 91752

Name: Pedricktown IDC UPS Healthcare
Address: 7 Gateway Blvd City: Pedricktown State: NJ Zip: 08067

Name: bioFire Diagnostics, LLC
Address: 1590 S 5200 W City: Salt Lake City State: UT Zip: 84104

Section 5: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): bioFire Holdings, Inc.
Corporation/Organization Name: bioFire Diagnostics, LLC
Mailing Address: 515 Colorow Drive
City: Salt Lake City State: UT Zip: 84108
Telephone: 636-399-4478 Email: statelicensing@biomerieux.com
Contact Person Name: Sandra Perreand

Section 7: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 8: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

bioFire Diagnostics, LLC

Facility Name

Sarah Mauney

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

07Jul27

Date

Board Use Only	Date Received: 7/15/26	Amount: $1000 CK 0000830344

Section 9: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 10: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale [a]Medical Products (medical devices, equipment, supplies, gases). (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Products (medical devices, equipment, supplies, gases), supply a copy of proof of insurance (NAC 639.6957).** The Medical Products wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 9)				
• **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20NRS%20639.500%20-%20Effective%2001.07.2026%20-%20Wholesaler%20-%20Post%20on%201.26.26.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
BioFire Diagnostics, LLC
Business Trade Name:
/F/K/A Idaho Technology, Inc.

515 Colorow Drive
Salt Lake City, UT 84108
Registration Number: 3002773840
FEI Number*: 3002773840
Status: Active
Date Of Registration Status: 2026

Owner/Operator:
BIOMERIEUX SA[6]
Chemin De L Orme
Marcy L Etoile Rhone 69280 FR
Owner/Operator Number: 8020790[7]

Official Correspondent:
Karli Plenert
515 Colorow Drive
Salt Lake City, UT 84108
Phone: 1-385-4144985

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

---

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&RegNum=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=8020790&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&RegNum=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=8020790&OwnerOperator

Page Last Updated: 07/20/2026

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsc | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of **Health & Human Services**

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&RegNum=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=8020790&OwnerOperator

Product Code	Description	Premarket Submission Number (510k):
NSU	BioFire FilmArray Torch instrument	K160068
PCH	BioFire FilmArray Gastrointestinal (GI) Panel	K242367
PCH	BioFire FilmArray Gastrointestinal (GI) Panel Mid	K243885
PLO	BioFire FilmArray Meningitis/Encephalitis (ME) Panel	K160462
QDP	BioFire FilmArray Pneumonia Panel	K243222
PEN, PEO, PAM	BioFire Blood Culture Identification 2 (BCID2) Panel	K243759
QOF	BioFire Respiratory Panel 2.1	DEN200031
QJR	BioFire Respiratory Panel 2.1-EZ	EUA (no longer on market)
QSN	BioFire Joint Infection (JI) Panel	DEN200066
QMV	BioFire FilmArray Tropical Fever Panel	K243463
NSU	BIOFIRE SPOTFIRE Module	K213954
QOF, OCC, OEM, OOU, OTG, OZE, OZX, OZY, OZZ	BIOFIRE SPOTFIRE Respiratory (R) Panel	K213954
QOF, OCC, OTG, OZE	BIOFIRE SPOTFIRE Respiratory (R) Panel Mini	K230719
QOF, OEM, OOU, OTG, OZE, OZX, OZY, OZZ, OCC, NSU, PGX	BIOFIRE SPOTFIRE Respiratory/Sore Throat Panel	K232954
QOF, NSU, OCC, OZE, PGX	BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel Mini	K243544

Attachment to bioFire Diagnostics, LLC's Out-of-State Wholesaler Application (Nevada Board of Pharmacy)

Description of Operations:
bioFire Diagnostics, LLC is a wholly-owned subsidiary of bioMérieux, Inc. bioFire Diagnostics, LLC ("bioFire") is an own-label manufacturer of In Vitro Diagnostic tests which includes both reagents and equipment. Our product is sold to wholesalers and directly to hospitals, and other health care delivery sites who provide diagnostic testing.

bioFire's office hours of operations are Monday through Friday from 8:00 a.m. to 5:00 p.m. MT.

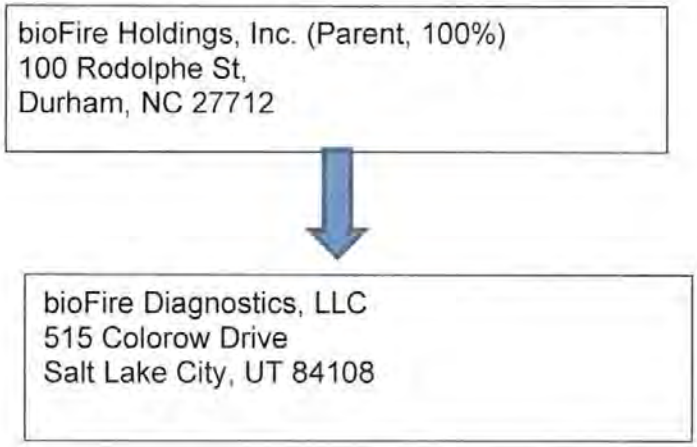
BioFire Diagnostics, LLC Directors and employees

Name	Title	Residence Address	Ownership %
Bart Van Den Brand	Sr. V.P. Site Operations Americas	[redacted]	0%
Sarah Mauney	V.P. General Counsel, Global Litigation N. America		0%

Parent Company:
BioFire Holdings, Inc. (100%)
100 Rodolphe St,
Durham, NC 27712

Attachment to bioFire Diagnostics, LLC's Out-of-State Wholesaler Application (Nevada Board of Pharmacy)

bioFire Diagnostics, LLC's Ownership



Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BIOFIRE DIAGNOSTICS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF MARCH, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "BIOFIRE DIAGNOSTICS, LLC" WAS FORMED ON THE TENTH DAY OF JANUARY, A.D. 2014.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 203317421

Date: 03-11-26

5463662 8300

SR# 20260512272

You may verify this certificate online at corp.delaware.gov/authver.shtml

Details for BioFire Diagnostics LLC

License Information

Name:

BioFire Diagnostics LLC

City, State, Zip, Country:

Salt Lake City UT 84104 United States

Profession:

Pharmacy

License Type:

Pharmacy - Class C

License Number:

14269401-1710

Obtained By:

Application

License Status:

Active

Original Issue Date:

03/25/2026

Expiration Date:

09/30/2027

Agency and Disciplinary Action*:

NO DISCIPLINARY ACTIONS WITHIN THE TIME FRAME ESTABLISHED IN UTAH CODE 63G-4-106 AND 107**

Docket and Citation Number(s):

N/A

E-Prescriber:

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LICENSE

BioFire Diagnostics LLC

EFFECTIVE
03/25/2026

EXPIRATION
09/25/2026

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

14269400-1710 Pharmacy - Class C

Manufacturer

DBA:

IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

BIOFIRE DIAGNOSTICS LLC
515 COLOROW DR
SALT LAKE CITY UT 84108

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE

DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING

ACTIVE LICENSE

EFFECTIVE DATE: **03/25/2026**

EXPIRATION DATE: **09/25/2026**

ISSUED TO: **BioFire Diagnostics LLC**
515 Colorow Dr
Salt Lake City UT 84108

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

14269400-1710 **Pharmacy - Class C** **Manufacturer**

DBA:

Details for BioFire Diagnostics LLC

License Information

Name:	BioFire Diagnostics LLC
City, State, Zip, Country:	Salt Lake City UT 84108 United States
Profession:	Pharmacy
License Type:	Pharmacy - Class C
License Number:	14269400-1710
Obtained By:	Application
License Status:	Active
Original Issue Date:	03/25/2026
Expiration Date:	09/25/2026
Agency and Disciplinary Action*:	NO DISCIPLINARY ACTIONS WITHIN THE TIME FRAME ESTABLISHED IN UTAH CODE 63G-4-106 AND 107**
Docket and Citation Number(s):	N/A
E-Prescriber:	
Specialty(s):	

Manufacturer

Reports require Adobe® Acrobat® Reader™.

This information is accurate as far as is contained in the Division's official records. It does not reflect whether an entity required to maintain a current registration with the Division of Corporations is current in that registration. You can verify such status at https://secure.utah.gov/bes/bes (opens in new window). Additionally, this verification does not show a complete license history or interruptions of licensure. Original issue dates listed as 01/01/1910 and 01/01/1911 were unknown at the time the Division implemented its first electronic licensing database.

*NOTE: The disciplinary documents linked to this website include final orders issued by DOPL, with the exception of citations. Click citations to view them online.

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 02/18/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Willis Towers Watson Midwest, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: WTW Certificate Center PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@wtwco.com
INSURED BioFire Diagnostics LLC 515 Colorow Drive Salt Lake City, UT 84108	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: Great Northern Insurance Company — 20303 INSURER B: Travelers Property Casualty Company of Ame — 25674 INSURER C: Federal Insurance Company — 20281 INSURER D: Travelers Casualty Company of Connecticut — 36170 INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** W43979510 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. *LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. LIMITS SHOWN ARE INCLUSIVE OF AMOUNTS REQUESTED BY THE CERTIFICATE HOLDER AND MAY NOT REFLECT POLICY LIMIT AMOUNTS IN EXCESS OF THOSE REQUESTED. ***Not Applicable in WY**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			99511735	01/01/2026	01/01/2027	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG Prod-CompOps Ea Occ	$ 2,000,000 $ 2,000,000 $ 10,000 $ 2,000,000 $ 2,000,000 $ 7,000,000 $ 7,000,000
B	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			HJ-CAP-9P532553-TIL-26	01/01/2026	01/01/2027	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
C	UMBRELLA LIAB X OCCUR X EXCESS LIAB CLAIMS-MADE DED RETENTION $			56720213	01/01/2026	01/01/2027	EACH OCCURRENCE AGGREGATE PROD COMP OPS AGG	$ 5,000,000 $ 5,000,000 $ Excluded
D	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		UB-A3449363-26-I2-E	01/01/2026	01/01/2027	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ 1,000,000 $ 1,000,000 $ 1,000,000
B	Excess Auto Liability			EX-9P532669-26-I2	01/01/2026	01/01/2027	Limit	$4,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence only

The GL Policy provides claims-made coverage for bodily injury and property damage included in the Products-Completed Operations Hazard.

Excess Auto Liability Follows Form of Underlying Auto

CERTIFICATE HOLDER

BioFire Diagnostics, LLC
515 Colorow Drive
Salt Lake City, UT 84108

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Mark Vit

© 1988-2025 ACORD CORPORATION. All rights reserved.

GENERAL SURETY RIDER

To be attached and form a part of

Bond No.	800227420
For	NV Pharmaceutical Wholesaler Bond - 100000 UP 1-23 (License & Permit) : License & Permit (900)
Dated effective	04/15/2026 (MONTH, DAY, YEAR)
Executed by	BioFire Diagnostics, as Principal, (PRINCIPAL)
And by	Atlantic Specialty Insurance Company, as Surety, (SURETY)
And in favor of	Nevada State Board of Pharmacy (OBLIGEE)

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

INFORMATION	
Adding Addresses for Service	515 Colorow DR Salt Lake City, UT 84108-1248 And 1590 S 5200 West Salt Lake City,UT 84104

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective **04/15/2026**

(MONTH, DAY, YEAR)

Signed and Sealed **04/15/2026**

(MONTH, DAY, YEAR)

BioFire Diagnostics

PRINCIPAL

BY _____

TITLE

Atlantic Specialty Insurance Company

SURETY

BY _____

Doritza Mojica, ATTORNEY-IN-FACT

intact INSURANCE

Surety Bond No: 800227420

Power of Attorney

BioFire Diagnostics
Nevada State Board of Pharmacy

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Doritza Mojica**, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON D. NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2030

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 15th day of April, 2026

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2030

_____
Kara L.B. Barrow, Secretary

Please direct bond verifications to surety@[illegible]

Telephone: +1 860 278 1320
Website: wtwco.com

April 17, 2026

BIOMERIEUX INC
Attn: Sarah Mauney
100 Rodolphe Street
Durham, NC 27712

RE: **April – New Bonds (8)**
April – Riders (8)
Commission: 32.5%

We are pleased to enclose the above referenced bond you requested. This bond was executed based upon the information you provided. We urge you to check all of the information enclosed, including the Power of Attorney, signatures, dates, amounts, description, bond form and any other attachments.

Please be sure to affix the bond with the proper signature and seal.

If a premium is charged, our invoice will follow under separate cover and premium payment for this bond is due upon receipt. **Please note that the first term's premium related to any renewable obligation is considered fully earned.**

Willis Towers Watson negotiates commission rates with certain insurers on a corporate level. If the rate on your placement is lower than the negotiated rate, Willis Towers Watson may collect the difference directly from the insurer. These payments will not increase the cost of your bonds or otherwise impact your premium or rates. Details of these arrangements where there is compensation beyond the base compensation detailed in your commission schedule can be found at: https://www.wtwco.com/en-us/notices/p-c-national-commission-rates.

Thank you for the opportunity to service your surety needs. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Rhi Portillo
Rhi.Portillo@wtwco.com

Willis Towers Watson Northeast, Inc.
10 State House Square, 11th Floor
Hartford, CT 06103

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 800227420

Application/License No. _____

BioFire Diagnostics (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1001 South 4800 West, Salt Lake City, UT 84104 (Address of Applicant/Principal), as PRINCIPAL, and Atlantic Specialty Insurance Company (Surety Company), a corporation organized under the laws of the state of NY (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 605 Highway 169 North, Suite 800 , Plymouth, MN 55441 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 15, 2026 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 15th day of April, 2026.

APPLICANT/PRINCIPAL

BioFire Diagnostics
COMPANY

By: _____
Authorized Representative

SURETY

Atlantic Specialty Insurance Company

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By: _____
Surety Company's Representative

Doritza Mojica, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

_____
Witness Haley Pulley

_____
Witness Makayla Alexis

Countersigned by:

_____
Nevada Resident Agent Malerie Janet Williams
Non-Resident License No.: 4156693

Posted February 20, 2020

intact INSURANCE

Power of Attorney

Surety Bond No: 800227420

BioFire Diagnostics
Nevada State Board of Pharmacy

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: _____ **Doritza Mojica** _____, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON D. NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2030

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 15th day of April 2026

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

_____
Kara L.B. Barrow, Secretary

This Power of Attorney expires
January 31, 2030

Please direct bond verifications to [illegible]

Telephone: +1 860 278 1320
Website: wtwco.com

April 17, 2026

BIOMERIEUX INC
Attn: Sarah Mauney
100 Rodolphe Street
Durham, NC 27712

RE: **April – New Bonds (8)**
April – Riders (8)
Commission: 32.5%

We are pleased to enclose the above referenced bond you requested. This bond was executed based upon the information you provided. We urge you to check all of the information enclosed, including the Power of Attorney, signatures, dates, amounts, description, bond form and any other attachments.

Please be sure to affix the bond with the proper signature and seal.

If a premium is charged, our invoice will follow under separate cover and premium payment for this bond is due upon receipt. **Please note that the first term's premium related to any renewable obligation is considered fully earned.**

Willis Towers Watson negotiates commission rates with certain insurers on a corporate level. If the rate on your placement is lower than the negotiated rate, Willis Towers Watson may collect the difference directly from the insurer. These payments will not increase the cost of your bonds or otherwise impact your premium or rates. Details of these arrangements where there is compensation beyond the base compensation detailed in your commission schedule can be found at: https://www.wtwco.com/en-us/notices/p-c-national-commission-rates.

Thank you for the opportunity to service your surety needs. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Rhi Portillo
Rhi.Portillo@wtwco.com

Willis Towers Watson Northeast, Inc.
10 State House Square, 11th Floor
Hartford, CT 06103

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG bioFire Diagnostics, LLC MDEG License # (if applicable) N/A

Physical Address 515 Colorow Drive

City Salt Lake City State UT Zip 84108

Mailing Address (if different from physical address) (Attn; Sandra Perreand c/o Mary Vomund, 595 Anglum Road

City Hazelwood State MO Zip 63042

Telephone 919-620-2000 Website www.biomerieux.com

Licensing Company Email statelicensing@biomerieux.com

Section 2: Personal Information

First Tyler Middle J Last Farrell

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 515 Colorow Drive

City Salt Lake City State UT Zip 84108

Telephone 919-620-2000 Email statelicensing@biomerieux.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Bridgerland Applied Technology College		2006	
Address	City	State	Zip
1301 N 600 W	Logan	UT	84321
Diploma/Degree obtained, if any			
Cabinetry			
School Name		From - To (MM/YY – MM/YY)	
Bear River High School		2002 - 20026	
Address	City	State	Zip
1450 S Main St	Garland	UT	84312
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2020 - Present	[redacted]	Layton	UT	[redacted]
From - To (MM/YY – MM/YY)		City	State	
2016 - 2020		Woods Cross	UT	
From - To (MM/YY – MM/YY)	Address	City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
BioFire Diagnostics, BioMerieux		2016 - Present	
Business Address	**City**	**State**	**Zip**
515 Colorow Drive	Salt Lake City	UT	84108
Phone	**Title**	**Number of Employed Hours**	
801-736-6354	Associate Director of Reagent Materials Management	20,800 Hours	
Description of Duties			
Procure			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question #_____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Tyler Jacob Farrell, **certify that as the MDEG Administrator for**

bioFire Diagnostics, LLC,

that I (initial that you have read and meet the following requirements):

1. TF Have a high school diploma or its equivalent;
2. TF Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. TF Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. TF Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tyler Farrell
Print Name (First, Last)

Tyler Farrell
Original Signature (electronic, copies or stamps not accepted)

05/12/2026
Date

Board Use Only	Date Received: 7/15/26

[redacted]

TYLER FARRELL

PROFILE

Reliable, professional, dedicated team player, ability to communicate effectively with others and possess leadership skills with a positive attitude.

REFRENCES

Available upon Request

KEY SKILLS

- Coaching and Development
- Communication
- Problem Solving
- Fast learner
- Adaptability

WORK EXPERIENCE

Associate Director of Materials Management

Biofire Diagnostics, BioMerieux, SLC Utah, 2016 – Current
Material Handler 09/2016-2018, Material Handler Team Lead 05/2018-2020 Materials Handling Manager 02/2020-2023, AD 02/2023-Current

STRATEGIC LEADERSHIP & PROGRAM EXECUTION

- Direct Material Strategy: Lead the end-to-end strategy, planning, and execution of material requirements for high-stakes diagnostic production, ensuring 100% availability of strategic components.
- Programmatic Risk Mitigation: Act as the primary focal point for cross-functional teams (Procurement, Quality, and Production) to identify supply chain gaps and execute mitigation plans for non-conforming materials.
- Executive Reporting: Brief Director-level leadership on key performance indicators (KPIs), including inventory status, service levels, and manufacturing support metrics to drive data-driven decision-making.
- Process Improvement: Defined and optimized GSC processes by instituting LEAN practices, including Six S, Value Stream Mapping, and FIFO, resulting in increased operational efficiency.

CROSS-FUNCTIONAL COLLABORATION

- Internal & External Liaison: Collaborate closely with the Program Management Office (PMO equivalent) and global supply base to ensure all material commitments meet rigorous business and quality requirements.
- Multi-Discipline Oversight: Manage multiple disciplines across the product life cycle, from incoming material requirements and receiving to production warehouse stocking and final delivery.

- Regulatory Compliance: Ensure 100% compliance with corporate policies and Quality Systems, supporting lot traceability and labeling for complex Manufacturing Execution System (MES) processes.

TEAM MANAGEMENT & DEVELOPMENT

- Leadership of Personnel: Supervise and mentor a diverse team of 10–20 personnel, overseeing professional development, performance evaluations, and technical training.
- Working Manager Excellence: Effectively manage competing priorities and tight deadlines in a fast-paced environment, maintaining a professional attitude while overseeing critical supply chain functions.

OPERATIONAL AUTHORITY

- Budget & Authority: Exercise signature authorization for production material planning and commit to supply base decisions with oversight from the Director of Supply Chain.
- Inventory Integrity: Facilitate comprehensive cycle count programs for finished goods and component materials, ensuring accuracy across centralized and production warehouses.

EDUCATION

- Bear River High School 2002-2006
  High School Diploma
- Bridgerland Applied Technology College, 2006 Cabinetry
- Trained in Planning and Inventory Management (CPIM I) 2022
- Lean Six Sigma Green Belt 2024

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: bioFire Diagnostics, LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 515 Colorow Drive

City: Salt Lake City State: UT Zip: 84108

Mailing Address (if different from physical address): (Same)

City: State: Zip:

Telephone: 801-736-6354 Website: www.biomerieux.com

Licensing Company Email: statelicensing@biomerieux.com

Section 2: Personal Information

First: Tyler Middle: Jacob Last: Farrell

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 515 Colorow Drive

City: Salt Lake City State: UT Zip: 84108

Telephone: 801-736-6354 Email: statelicensing@biomerieux.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Bridgerland Applied Technology College		2006	
Address	City	State	Zip
1301 N 600 W	Logan	UT	84321
Diploma/Degree obtained, if any			
Cabinetry			

School Name		From - To (MM/YY – MM/YY)	
Bear River High School		2002 - 2006	
Address	City	State	Zip
1450 S Main St	Garland	UT	8431
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2020 - Present	[redacted]	Layton	UT	[redacted]
2016 - 2020		Woods Cross	UT	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
BioFire Diagnostics, BioMerieux			2016 - Present	
Business Address		City	State	Zip
515 Colorow Drive		Salt Lake City	UT	84108
Phone	Title		Number of Employed Hours	
801-736-6354	Associate Director of Reagent Materials Management		20,800 Hours	
Description of Duties				
Resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
N/A				
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
N/A				
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6/23/2026
Date

I, Tyler Farrell, **certify that as the designated representative for**

bioFire Diagnostics, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TF I am at least 21 years of age;
3. TF I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TF I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TF I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TF I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TF I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Tyler Farrell
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/23/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tyler Farrell
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/23/2026
Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Salt Lake

I, Tyler Farrell, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/23/2026
Date

Subscribed and Sworn to before me this 23 day of June 2026

Notary Public Signature

KELLY OAKS
Notary Public - State of Utah
Comm. No. 734347
My Commission Expires on
Nov 27, 2027

(Seal)

Name
Aaron ATNIP
Aaron BANOBI
Aaron GREER
Abdulrashid BAKARE
Abigail JENKINS
Abigail KOVASH
Adam ANDRUS
Adam DANIELS
Adam DIETZ
Adam MILLINGTON
Adam SWENSON
Ajak AROK
Alan MORTENSEN
Alan VAWDREY
Albert FREI
Aldo MENDEZ
Alec MCKENZIE
Alejandra MOLINA
Alejandro PADILLA
Alex CESPEDES
Alex LONGORIA
Alex SMITH
Alex TAYLOR
Alex VELASQUEZ
Alexander BURNETT
Alexander DUTTON
Alexander KIM
Alexander PAPPAS
Alexander RODAS
Alexander SANDERS
Alexander SMIRNOV
Alexander TAYLOR
Alexandra SUFIT
Alifia JAKAMARTANA
Alison TARGOSKY
Allison ANDREWS
Alyssa ABRAHAM
Alyssa NGO
Alyssa WILLIAMS
Amanda TAPUSOA
Ambika MAGAR
Ami IVERSON
Amivi AFATCHAO
Ana GRANADOS

Ana SOMA
Analia QUIRK
Anastasia MOSS
Andre Ana PENA
Andrea ALVAREZ
Andrea MACHALEK
Andrew ANDERSON
Andrew CHRISTENSEN
Andrew ENGLAND
Andrew HEMMERT
Andrew HURLBUT
Andrew PETERS
Andrew PETERSON
Andrew PULSIPHER
Andrew WEST
Andy LE
Angela CLARK
Angelina CANCINO-BEDOLLA
Angellene CATAUSAN
Ann DEMOGINES
Anna CARUSO
Anna HURLOCK
Annabelle HEATON
Anne ANNE
Ansley BAUTCH
Anthony GONZALEZ
Anthony PALERINO
Antoinette BLOM
Antonio AYALA
Antonio WILLIAMS
April NGUYEN
Arianne FRANCIS
Ariel PIERCE
Arin PUTNAM
Ariosto FERRO
Arliss ANTONIO
Arnel BESIC
Ashley HILLMAN
Ashley KY
Ashley LEMOS
Ashley PACHECO
Ashley STEPHAN
Ashley WESTOVER
Aurelie KAPUSTA
Austin BOONE

Austin FASHIMPAUR
Austin SCHEMBRI
Austin VECCHIO
Bart KENSINGER
Bartek KSOK
Beki HEATH
Ben HENDRICKS
Ben VAN HOOSE
Benjamin ANDERSON
Benjamin HARMON
Benjamin MCMILLAN
Benjamin OLIVER
Bentley HOLYOAK
Bethany HEARST
Blake GAPIK
Blanca RAMIREZ
Boden ARCHULETA
Brad GRAHAM
Braden ROGERS
Bradley RACEY
Brady WILLIAMS
Brandon FOLEY
Brandon HANBERG
Brenda TIDWELL
Brendon NORRIS
Breton DAY
Brett DOWDEN
Brett GILBERT
Brian DORCHEUS
Brian FERGUSON
Brian JONES
Brian WALLIS
Brianne HAMILTON
Brittany KOSTIHA
Brockton GONZALES
Bronw KHOUANPHET
Brook MOULDER
Brooke ADAM
Brooke PETERSON
Brooklyn DARBY
Brooklyn NAWROCKI
Bruce JONES
Bryan ELDREDGE
Bryant SMITH
CaBri MONTANO

Caitlin CASTANEDA
Calder LAKE
Caleb FELICETTI
Callie SCULL
Calvin GRIMM
Calvin TU
Camden JENSON
Cameron HILL
Camron SHERMAN
Camryn THOMPSON
Candelaria RAMIREZ
Carl TINCHER
Carlos BONIFASI-LISTA
Carlos HERNANDEZ
Carlos RODRIGUEZ
Carrie COOK
Celestin UNGEYI
Celine MARTIN ROGER DALBERT
Cesar SALVADOR
Chad RUSSELL
Chanwoo CHOI
Chaoying LI
Charles KUISMI
Charles MCNALL
Charlie DIEP
Chase BOURGEOUS
Chase CHRISTISON
Chelsea BUBA
Chelsea GOSNEY
Chenda VANN
Cheryl BAIRD
Cheryl ZAPATA-ALLEGRO
Chizuko RAWLINGS
Chloe YOUNG
Christian ALLRED
Christian MERRILL
Christina GARDINER
Christina NEFF
Christopher ANJEWIERDEN
Christopher BRADFORD
Christopher MARTIN
Christopher MORGAN
Christopher MORROW
Christopher OLSEN
Christopher SOUTHER

Christopher ZDUNICH
Clara Dawn SEPULVEDA
Clark ROPER
Claudia CASTELLANOS
Claudia VALLADARES
Cody ANDERSON
Cody CHRISTIANSON
Cody FIRMAGE
Cody OSWALD
Cody WAREHAM
Colin BEAUVAIS
Connor WEEMS
Conor OSULLIVAN
Cory RINDLISBACHER
Courtney BUCKLEY
Courtney NUNN
Craig CHANDLER
Craig RODDIN
Craig SMITH
Crystal SMITH
Cynthia ANDJELIC
Cynthia LEW
Daisy GUTIERREZ-MATIAS
Daisy TRUONG
Dalton DAVIS
Damian SHELTON
Damien HOCH
Dan YOUNGBERG
Dana BROWN-ABLING
Dana SAIF
Dane LARSEN
Dane WIKSTROM
Daniel DANGERFIELD
Daniel ENCE
Daniel FRAME
Daniel GOMM
Daniel NGUYEN
Daniel REYES
Daniel RIVERA ESPADA
Daniel STURM
Daniel YOUNGERMAN
Danielle GAZTAMBIDE
Danielle RICHARDSON
Dardan SADRIJA
Daria DROBYSHEVA

Darrell PERRY
Darrell ROBERTS
David ACUNA-SUESCUN
David ASMAN
David DUBA
David HAMMOND
David HENDERSON
David HULET
David WALKER
Dayton GOODELL
Deja HERRERA
Demetrius HAMILTON
Deondre VAUGHAN-WATSON
Derek CASTILLO
Derek CONDIE
Derek MACHALEK
Devin SOTO
Diana GRANADOS ALCARAZ
Dillon DAY
Dirk COOLEY
Dominic CAPUTO
Douglas HILLSON
Douglas SANTOS
Duncan BRUNSTETTER
Duncan FURGESON
Dustin WHITE
Dustin WILBURG
Dustin ZITTING
Dyson ROSS
Eduardo ACEVEDO LUGO
Eduardo PANTOJA
Eduvijes DE LA HOYA
Edward HILL
Elaine SLECHTA
Eleanor HORROCKS
Elias PECCHIA-BEKKUM
Eliot NAGLER
Elissia BLAKE
Elizabeth BROWN
Elizabeth COPENE
Elizabeth COTTER
Elizabeth FINE
Elizabeth VIRGEN
Ellee HALL
Ellie MCLAIN

Elliott BARCIKOWSKI
Elliott MARSDEN
Emily GREULICH
Emily LUTZ
Emily RADIVOYEVICH
Emma HEALEY
Emma LADO
Emmanuel MUTANGANA
Ena MUHAREMOVIC
Enrico JUAREZ
Eric AIU
Eric DASTRUP
Eric HEUFT
Eric KLEIN
Erik HUYNH
Erik MISIAK
Erik THOMAS
Erika PENUNURI GUERRERO
Erin BILLS
Erin FLORESCA
Erin JAMAR
Ervin CHHOUR
Eryn HANSON
Estela ESTRADA NUNEZ
Ethan PEDERSEN
Eun Seo KIM
Evan BONAR
Ewing GREEN
Faith NOBLE
Faizuly SANCHEZ
Fedra ROJAS MARTINEZ
Felicia WALDIE
Flaviano GARCIA
Flaviano GARCIA
Flor LAZO
Freddy SUYOTO
Frederick ZWIRB
Gabriel JOB
Gabriel URBINA
Gale CURRY JR.
Gareth GRAVES
Garrett CROSBY
Garrett HOLMAN
Garrett ROBERTS
Garry STOOR

Gary SNOW
Gavin TURNER
Georgi DUNGAROV
German ACOSTA
Gerrie RICHARDSON
Gersonh GOMEZ RINCON
Giselle ZAMUDIO-FRAUSTO
Glade KNIGHT
Gladis CAIZEROS
Grant MATHESON
Gregg TALIERCIO
Gregory ANTONINI
Gregory FEUCHT
Gregory GNOS
Gregory SHATTUCK
Hana BAY
Hannah BRUNS
Hannah Louise LANDICHO
Harvey FRANCO
Hasan ALSHAYEB
Hawta HAMA
Hayden PACK
Heather EYRE
Heather KLUK
Heather THORSTENSON
Heather WILKERSON
Hebah BOKHARI
Hector DIAZ
Heidi BUTZ
Heidi NICHOLS
Helen ELIA
Henrik OBRIEN
Henry THOMPSON
Herman BUENAVISTA
Holly HENDERSON
Huali GUO
Hunter CASPER
Hunter HAUSER
Ian PELZER
Ignacio CHAIREZ
Ignatius CHAKUNDURA
Irene ELLIOTT
Irshad SIAL
Isaac FAIT
Isabel LOPEZ

Isabella JAMU
Isabelle INTERDONATO
Isaiah WILDE
Ivan ALVAREZ
Ivy KELLER
Jack KOEPKE
Jackson HILL
Jacob BARES
Jacob HIRST
Jacob MESSER
Jacob STANTON
Jacqueline HIDALGO DE MATA
Jake HEHR
Jake MORRIS
James ANDERSON
James HUNTINGTON
James MALONE
Jameson MCCARTY
Jamey HULSBERG
Jami SHANE
Jamihl BRAIMAH
Jamon ROBERTS
Jana BANGERTER
Jared GOOS
Jared HAYES
Jarrod LAFOUNTAIN
Jasmine SCOTT
Jason ELLSWORTH
Jason JORGENSEN
Jason MALKIN
Jason PATTERSON
Jay JONES
Jedediah CLARKE
Jefferson HAFFENER
Jeffery SEVY
Jeffrey BASTAR
Jeffrey DAVIS
Jeffrey KHOUNMOUANG
Jeffrey WILLIAMS
Jenifer EINSTEIN
Jenna LATIMER
Jennifer BLALOCK
Jennifer STIFFLER
Jenny KING-SCALES
Jenny KRYSTKOWIAK

Jeremiah ANTOSCH
Jeremiah POPE
Jeremy FILLIS
Jeremy GREEN
Jeremy GREER
Jeremy ROLLER
Jerry MOSS
Jesse LAJUAN
Jessenia MORENO
Jessica MARTIN
Jessica MUSE
Jessica STONE
Jessica WICKS
Jeunome ACHENJANG
Jimmy SANDOVAL
Jing ZHOU
Jo Anne SYMONETTE
Jocabeth PINEDA CURIEL
Jocelyn TODD
Jodi WILLIAMS
Joe STANTON
Joel MANWARING
John ANDERSON
John BURTON
John DICKEY
John MIDDLETON
John WISNIEWSKI
Jonathan CRITES
Jonathan DANSIE
Jonathan MECHAM
Jonathan SALAS NAVARRO
Jordan KOOP
Jordyn GERBER
Jorge FRIAS
Joseline FUENTES
Joseph CONDER
Joseph GILMORE
Joseph HATCH
Joseph KELLEN
Joseph KENT
Joseph LAUCHNOR
Joseph PASSEY
Josh GUBLER
Joshua ARNDT
Joshua COOMBS

Joshua DAVIS
Joshua EWELL
Joshua KUHRE
Joshua MCMILLAN
Joshua OAKS
Joshua SOUTHWICK
Joshua TEERLINK
Joshua TUNICK
Josie CALDER
Juan NUNEZ
Judith ORULLIAN
Julie CORNWALL
Julie IMBURGIA
Justin BROWN
Justin KEENER
Justin NUTTALL
Justin OLDFATHER
Justin TIDWELL
Justine LAMM
Justine LIANG
Kaitlyn NOHRENBERG
Kaitlyn PARKINSON
Kaitlyn STOOR
Kaleb ZICK
Karen BAUMAN
Karen FRAZER
Karima MOUMENE
Karina BIANCONE
Karla TRUJILLO
Kasandra JONES
Kasey FISHER
Katelyn FROEHLICH
Katharine BARNARD
Katherine GREEN
Katherine PARRA
Katherine SNYDER
Kathleen BOWEN
Katie BALDWIN
Katie FERNANDEZ LOPEZ
Keana AIU
Keegan BATE
Keith BARNES
Keith NEBEKER
Kelcey HOGAN
Kelsey HUNZIKER

Kelvin UZZELL
Kendall RASBAND
Kenneth DUNN
Kenneth HUBBARD
Kenneth ROWE
Kenton LOVE
Kenza ENRIGHT
Kenzon FERDINAND
Kera NIELSEN
Kerrin HALO
Kevin BOURZAC
Kevin MENEGOS
Kidi OJWATO
Kiersten KOLZ
Kimberly MEPHAM
Kiran BORA
Klinton STARR
Korban LEHMAN
Kristel BORSOS
Kristen HOLMBERG
Kristen STRINGHAM
Kristin KRENEK
Kristina NOLFF
Kristy ONG
Kseniya BEYLINA
Kurtis LOVE
Kwinton PYNE
Ky LAMOUREUX
Kyer HARRIS
Kylaya WEBER
Kyle ERICKSON
Kyle MELZER
Kyle MIKA
Kyle TRAN
Kyler ADKINS
Kylie SAGE
Lake ANDERSON
Lance HADERLIE
Lance LARSEN
Landen ANDRA
Landon KASTEN
Laura AH LOO
Laura ANTHONY
Laura DICKEY
Lauren ANDERSON

Lauren BROWN
Lauren EADS
Lauren Isabella TOTANES
Lauren ROBERTS
Lauren SPANBAUER
Lauren STROHACKER
Leonard CURRY
Leonardo LEANO
Levi FIFIELD
Lijun WEBB
Lindsay JOHNSON
Lindsay WILDE
Linnea HALL
Lisa OGDEN
Lorin BROOKES
Lorin PALEY
Louanne OLSEN
Lucas SMITH
Lucero SARINANA
Luke COTTER
Lyle NAY
Macoy KENNEDY
Madelyn NOUFER
Mae-Lynn HUTCHINSON
Maggie BUCCAMBUSO
Mahmoud AWADA
Mahoro SAFARI
Malini RAJAN
Mallira NOLASCO
Mallory WEAVER
Manasa GUDHETI
Manuel LUCENA
Maraia ULUAVE
Marcie LEEK
Marco AGUILERA
Marcus MATTOX
Maren RAWLINS
Margarita ROGATCHEVA
MariLar GRAFF ZARZOSA
Maria CANSINO
Maria Del Carmen CAMPBELL
Maria LUCAS
Maria URCINO
Mariah WEATHERFORD
Marina PIMENTEL

Mario MACIAS
Mark MIDDLETON
Mark STREVAY
Mark WENZEL
Marlee POTI
Marshall MAUGHAN
Marta MANGIFESTA
Marta SCHAUB
Martha JOHNSON
Martina YANKEE
Maru TORRES
Mary PETERSON
Mary ROTH
Mason BUCKMAN
Mathew MORTON
Matthew ADAMSON
Matthew BARBER
Matthew BERGSTROM
Matthew BOXX
Matthew BRYCE
Matthew COX
Matthew FRANDSEN
Matthew HOCKIN
Matthew JONES
Matthew MUNOZ
Matthew MURDOCK
Matthew NAVAREZ
Matthew OWEN
Matthew PEDERSEN
Matthew POULSON
Matthew WHITE
Maysa MUHSEN
McKade HERMANSEN
McKenna LATTEIER
Megan BORNSTEIN
Megan FORSBERG
Megan GIBSON
Megan MAJOR
Megan TRAVER
Megan WELSH
Meghan KUEHN
Meghan SCHAFFER
Melanie OGDEN
Melina TALO
Melissa GRIFFITH

Melville HELD
Melynda LINDHORST
Mercedes TIRADO
Meredith PEEBLES
Michael AGARUWA
Michael BOETTCHER
Michael DALE
Michael FORSYTH
Michael GALIETTI
Michael GRAY
Michael HEINZ
Michael JESKE
Michael JOHNSON
Michael JULIAN
Michael LUNT
Michael SEGURA
Michael VAUGHN
Michaela ABEYTA
Michaela POWELL
Michelle MARCO
Michelle STOLLER
Mick CROSS
Mikai LAMB
Miriam MUJICA CORNEJO
Mitchell QUETANT
Monica CRONIN
Monica PHEA
Monte ANDERSEN
Morgan BENNETT
Morgan BISHOP
Myer MOONEY
Nakelle GOLDIE
Nanasi SEKONA
Natalie HARRIS
Natalie PUPUNU
Natalie ROBINSON
Nathan EREKSON
Nathan KING
Nathan MATHEWS
Nathan MILLER
Nathan REDMAN
Nathan SPENCER
Nicholas PROTONENTIS
Nicholas WARNER
Nichole ALLRED

Nickolas BLANK
Nicolas CALACINO
Nicole CENTENO
Nicole MONROE
Nicole SMITH
Nicole URBINA
Nikola WILLIAMS
Nolan WEBER
Ojulu CHAM
Olena LUKINOVA
Olivia HARRIS
Oo REH
Oscar ESPARZA
Oswaldo PONCE DE LEON LANDA
Paige LANE
Parker ABEGG
Parker BENGTZEN
Parker CHILDS
Parker MABEY
Parker O'BRAY
Parker ROBINSON
Patricia KEENE
Patricia MANCILLA
Patricio HUAIQUIMILLA CASTRO
Paul SOLOMON
Paul WYNN
Pedro CORONA
Perry BROWN
Phan MOTAGHED
Phillip MELFI
Porter PATANE
Prabesh KHAPANGI
Prabesh LOHANI
Priya MAGIYA
Rachael GULBRANDSEN
Rachael PULLEY
Rada JANJIC
Raven HERNANDEZ
Ray JENNINGS
Ray MARTIRIZAR
Rayito ALVAREZ
Rebekah HARDMAN
Rebekah STEWART
Renovat MBONIMPA
Renzel CAMARINES

Reuben ROBIE
Rex BAKER
Richard ANDREW
Richard GUNDERSON
Richard SKINNER III
Rita ROMAN RODRIGUEZ
Rob JOHNSON
Robert BROWN
Robert BYRON
Robert HOBSON
Robert KIRSCHNER
Robert KOELLIKER
Robert PAYNE JR
Robert ROBISON
Robert RUDZIK
Robert TRAUSCHT
Rodney POPE
Ron MUDROW
Rudy ZAMORA
Ruijin YE
Russell GREEN
Ruth-Ann KING
Ryan BURKE
Ryan GUERRICABEITIA
Ryan HAHN
Ryan LIPSCOMB
Ryan STEPP
Ryan STETTLER
Ryan VANDYKE
Sabrina STAPLEY
Sajde VENARI
Sam BUCKLEY
Sam JENSEN
Samantha HILL
Samantha KING
Samantha MARTINEZ
Samantha VERDE
Samuel BALMANNO
Samuel JEWETT
Samuel LASCH
Samuel MCCLENDON
Samuel NAATZ
Samuel SCHMIETT
Samuel STEPHENSON
Samuel WILSON

Sandy VO
Sapna VISHWANATH
Sarah DEMARIA
Sarah GROSS
Sarah HAYES
Sarah RIPLEY
Sarah SAFRAN
Sarah SMITH
Sasha THOMPSON
Satya BELLAMKONDA
Scott ANDREWS
Scott BIDDINGER
Scott WALTON
Scott WILLIAMS
Sean ARGONDIZZA-MOBERG
Sean EVANS
Sean FINLEY
Sean KATHREIN
Sean STRAIN
Seohee PARK
Sergio CASTANON-DIAZ
Serra OZGEN
Shaless PARKER
Shannon FEELEY
Shannon MCCALLUM
Shaun MILLER
Shawn GORDON
Shelly COLEMAN
Sierra HOGE
Skyler MERRY
Sokha KUEHN
Somruethai SUSIRIWATANANONT
Soren WOOD
Spencer HOON
Spencer KIPFMUELLER
Stacey TURPIN
Stefanie MARXREITER
Stefannia ESPARZA PULIDO
Stephanie FAIRES
Stephanie HUMPHREY
Stephanie VANBEUGE
Stephen OLSEN
Stephen VICCARONE
Stephen WASMUND
Stephen WILLIAMS

Steven ALAM
Steven ANDERSON
Steven HAFT
Steven MURGUIA
Stewart SMITH
Sullivan PHETCHANPHENG
Sydney ARENA
Talissa MEZA
Tanner CHAMBERLAIN
Tanner HATCH
Tanner ROBINSON
Tanya NIETO
Tarek MOUSTAFA
Tarik VU
Taylor BRANDT
Taylor BYBEE
Taylor FADGEN
Taylor ZIMMERMAN
Tayne HELSEL
Ted KOHLMANN
Tej MAGAR
Teon STRONG
Terral MICHAELSON
Tessa LIVOTI
Thane STORLEY
Thao Vy NGUYEN
Theodore WILSON
Theresa SOSA TARELO
Thien-Kim TANG
Thomas KEEFE
Thomas NEWELL
Thomas RICHES
Thomas ROBBINS
Thomas WATKINS
Thurman LEE
Tiffany CHRISTENSEN
Tim KRUMWIEDE
Timothy CRAMER
Timothy WELKE
Toan PHAM
Todd MADSEN
Toma TODOROV
Toni MUND
Tony LUU
Tonya MORTENSON

Traci HAYES
Traci SHAW
Tracy DUNBAR
Tracy PIERCE
Trent CROFT
Trent HEATH
Trenton BELKA
Trenton MORRISON
Trevor OLSEN
Trevor TAYLOR
Trinity METCALF
Trisha MCFARLAND
Tristan BOWLER
Tucker STEWART
Ty LARSEN
Tyler HALL
Tyler HEALY
Tyler SACCO
Tyrus DRAPER
Tyson DAWSON
Usha SPAULDING
Valeria QUINONES-CRUZ
Vanessa CAMACHO
Vannarith LY
Vianey TREJO
Vickey BUTTERS
Victor CUENCA AGUILAR
Victor VIVEROS
Victoria KRAWIEC
Victoria VANCE
Vivienne BLACK
Vladyslav BOYKO
Vy VO
Wade VESELKA
Wesley COOK
Weston MORLEY
Whitney KENNER
William COGGUILLO
William GARRETT
William MARRINGA
William RICHARDS II
Xiaofen WANG
Yannick VAN HUELE
Yi ZHANG
Yinying HATTON

Yolva LOYA-SALINAS
Zachariah YOUNG
Zachary BERGMAN
Zachary BORLAND
Zachary CHILD
Zachary DALTON
Zachary DUTCHER
Zachary MCDOUGALD
Zachery COTE
Zane YARBROUGH
Zechariah DEVICK
Zheng ZHOU
Zhenmei LU

4R

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10) ■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10)

Section 1: General Information

Facility Name: bioFire Diagnostics, LLC

Physical Address: 1001 S 4800 W

City: Salt Lake City State: UT Zip: 84104

Mailing Address (if different from physical address): Attn; Sandra Perreand c/o Mary Vomund, 595 Anglum Road

City: Hazelwood State: MO Zip: 63042

Telephone: 801-736-6354 Website: www.biomerieux.com

Name of Designated Representative (DR): Linsey Page

Licensing Company Email: statelicensing@biomerieux.com DR Email: statelicensing@biomerieux.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies ☐ Practitioners ■ Hospitals ■ Wholesalers ☐ Veterinarians ☐ Others:	☐ Dangerous Drugs ☐ Controlled Substances ■ [a]Medical Products (medical devices, equipment, supplies, gases) ☐ Others: in vitro diagnostic tests, reagents and equipment	■ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ■ Others: Medical Devices

Section 2: ONLY COMPLETE THIS SECTION IF THE COMPANY IS WHOLESALING [a]Medical Products (medical devices, equipment, supplies and gases). Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 3 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

07/2026
Date

Section 4: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Louisville IDC UPS Healthcare
Address: 2260 Outer Loop City: Louisville State: KY Zip: 40219

Name: Mira Loma IDC UPS Healthcare
Address: 11991 Landon Dr City: Mira Loma State: CA Zip: 91752

Name: Pedricktown IDC UPS Healthcare
Address: 7 Gateway Blvd City: Pedricktown State: NJ Zip: 08067

Name: bioFire Diagnostics, LLC
Address: 1590 S 5200 W City: Salt Lake City State: UT Zip: 84104

Section 5: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): bioFire Holdings, Inc.
Corporation/Organization Name: bioFire Diagnostics, LLC
Mailing Address: 1001 S 4800 W
City: Salt Lake City State: UT Zip: 84104
Telephone: 636-399-4478 Email: statelicensing@biomerieux.com
Contact Person Name: Sandra Perreand

Section 7: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 8: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 9: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 10: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale [a]Medical Products (medical devices, equipment, supplies, gases). (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Products (medical devices, equipment, supplies, gases), supply a copy of proof of insurance (NAC 639.6957).** The Medical Products wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 9)				
• **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20NRS%20639.500%20-%20Effective%2001.07.2026%20-%20Wholesaler%20-%20Post%20on%201.26.26.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

bioFire Diagnostics, LLC

Facility Name

Sarah Mauney

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

07/24/26

Date

Board Use Only	Date Received: 7/15/26	Amount: $1000 Ck 0000830343

Attachment to bioFire Diagnostics, LLC's Out-of-State Wholesaler Application (Nevada Board of Pharmacy)

Description of Operations:

bioFire Diagnostics, LLC is a wholly-owned subsidiary of bioMérieux, Inc. bioFire Diagnostics, LLC ("bioFire") is an own-label manufacturer of In Vitro Diagnostic tests which includes both reagents and equipment. Our product is sold to wholesalers and directly to hospitals, and other health care delivery sites that provide diagnostic testing.

bioFire's office hours of operations are Monday through Friday from 8:00 a.m. to 5:00 p.m. MT.

BioFire Diagnostics, LLC Directors and employees

Name	Title	Residence Address	Ownership %
Bart Van Den Brand	Sr. V.P. Site Operations Americas	[redacted]	0%
Sarah Mauney	V.P. General Counsel, Global Litigation N. America		0%

Parent Company

BioFire Holdings, Inc. (100%)
100 Rodolphe St,
Durham, NC 27712

Attachment to bioFire Diagnostics, LLC's Out-of-State Wholesaler Application (Nevada Board of Pharmacy)

bioFire Diagnostics, LLC's Ownership

bioFire Holdings, Inc. (Parent, 100%)
100 Rodolphe St,
Durham, NC 27712



bioFire Diagnostics, LLC
1001 S 4800 W
Salt Lake City UT 84104

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BIOFIRE DIAGNOSTICS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF MARCH, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "BIOFIRE DIAGNOSTICS, LLC" WAS FORMED ON THE TENTH DAY OF JANUARY, A.D. 2014.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5463662 8300

SR# 20260512272

Authentication: 203317421

Date: 03-11-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LICENSE

BioFire Diagnostics LLC

EFFECTIVE 03/25/2026

EXPIRATION 09/25/2026

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)
14269401-1710 Pharmacy - Class C

Manufacturer

DBA:

IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

BIOFIRE DIAGNOSTICS LLC
1001 S 4800 W
SALT LAKE CITY UT 84104

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE
DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING
ACTIVE LICENSE

EFFECTIVE DATE: **03/25/2026**

EXPIRATION DATE: **09/25/2026**

ISSUED TO: **BioFire Diagnostics LLC**
1001 S 4800 W
Salt Lake City UT 84104

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

14269401-1710 **Pharmacy - Class C** **Manufacturer**

DBA:

Form #1

Details for BioFire Diagnostics LLC

License Information

Name:

BioFire Diagnostics LLC

City, State, Zip, Country:

Salt Lake City UT 84104 United States

Profession:

Pharmacy

License Type:

Pharmacy - Class C

License Number:

14269401-1710

Obtained By:

Application

License Status:

Active

Original Issue Date:

03/25/2026

Expiration Date:

09/30/2027

Agency and Disciplinary Action*:

NO DISCIPLINARY ACTIONS WITHIN THE TIME FRAME ESTABLISHED IN UTAH CODE 63G-4-106 AND 107**

Docket and Citation Number(s):

N/A

E-Prescriber:

Product Code	Description	Premarket Submission Number (510k):
NSU	BioFire FilmArray Torch instrument	K160068
PCH	BioFire FilmArray Gastrointestinal (GI) Panel	K242367
PCH	BioFire FilmArray Gastrointestinal (GI) Panel Mid	K243885
PLO	BioFire FilmArray Meningitis/Encephalitis (ME) Panel	K160462
QDP	BioFire FilmArray Pneumonia Panel	K243222
PEN, PEO, PAM	BioFire Blood Culture Identification 2 (BCID2) Panel	K243759
QOF	BioFire Respiratory Panel 2.1	DEN200031
QJR	BioFire Respiratory Panel 2.1-EZ	EUA (no longer on market)
QSN	BioFire Joint Infection (JI) Panel	DEN200066
QMV	BioFire FilmArray Tropical Fever Panel	K243463
NSU	BIOFIRE SPOTFIRE Module	K213954
QOF, OCC, OEM, OOU, OTG, OZE, OZX, OZY, OZZ	BIOFIRE SPOTFIRE Respiratory (R) Panel	K213954
QOF, OCC, OTG, OZE	BIOFIRE SPOTFIRE Respiratory (R) Panel Mini	K230719
QOF, OEM, OOU, OTG, OZE, OZX, OZY, OZZ, OCC, NSU, PGX	BIOFIRE SPOTFIRE Respiratory/Sore Throat Panel	K232954
QOF, NSU, OCC, OZE, PGX	BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel Mini	K243544

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 01/15/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Willis Towers Watson Midwest, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	**CONTACT NAME:** WTW Certificate Center **PHONE (A/C, No, Ext):** 1-877-945-7378 **FAX (A/C, No):** 1-888-467-2378 **E-MAIL ADDRESS:** certificates@wtwco.com
INSURED bioMérieux, Inc. 1001 South 4800 West Salt Lake City, UT 84104	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A:** Great Northern Insurance Company — 20303 **INSURER B:** Travelers Property Casualty Company of Ame — 25674 **INSURER C:** Travelers Casualty Insurance Company of Am — 19046 **INSURER D:** **INSURER E:** **INSURER F:**

COVERAGES **CERTIFICATE NUMBER:** W43675212 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			99511735	01/01/2026	01/01/2027	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG Prod-CompOps Ea Occ	$ 2,000,000 $ 2,000,000 $ 10,000 $ 2,000,000 $ 2,000,000 $ 7,000,000 $ 7,000,000
B	AUTOMOBILE LIABILITY [X] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY			HJ-CAP-9P532553-TIL-26	01/01/2026	01/01/2027	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
	[ ] UMBRELLA LIAB [ ] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $						EACH OCCURRENCE AGGREGATE	$ $ $
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [ ] (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		UB-A6552544-26-I2-K	01/01/2026	01/01/2027	[X] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
B	Workers Compensation (AZ, MA, WI) Per Statute			UB-A6550133-26-I2-R	01/01/2026	01/01/2027	E.L. EACH ACCIDENT E.L. DISEASE - EA EMP E.L. DISEASE-POL LMT	$1,000,000 $1,000,000 $1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

The GL Policy provides claims-made coverage for bodily injury and property damage included in the Products-Completed Operations Hazard.

SEE ATTACHED

CERTIFICATE HOLDER

Evidence of Coverage

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

© 1988-2016 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

SR ID: 29227029 BATCH: 4281098

AGENCY CUSTOMER ID: _____

LOC #: _____

ACORD®

ADDITIONAL REMARKS SCHEDULE

AGENCY		NAMED INSURED
Willis Towers Watson Midwest, Inc.		bioMérieux, Inc. 1001 South 4800 West Salt Lake City, UT 84104
POLICY NUMBER See Page 1		
CARRIER See Page 1	NAIC CODE See Page 1	EFFECTIVE DATE: See Page 1

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

INSURER AFFORDING COVERAGE: Travelers Property Casualty Company of America NAIC#: 25674

POLICY NUMBER: EX-9P532669-26-I2 EFF DATE: 01/01/2026 EXP DATE: 01/01/2027

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Excess Auto Liability	Limit	$4,000,000

ADDITIONAL REMARKS:

Excess Auto Liability Follows Form of Underlying Auto

ACORD 101 (2008/01)

© 2008 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

SR ID: 29227029 BATCH: 4281098 CERT: W43675212

GENERAL SURETY RIDER

To be attached and form a part of

Bond No.	800227420
For	NV Pharmaceutical Wholesaler Bond - 100000 UP 1-23 (License & Permit) : License & Permit (900)
Dated effective	04/15/2026 (MONTH, DAY, YEAR)
Executed by	BioFire Diagnostics, as Principal, (PRINCIPAL)
And by	Atlantic Specialty Insurance Company, as Surety, (SURETY)
And in favor of	Nevada State Board of Pharmacy (OBLIGEE)

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

INFORMATION	
Adding Addresses for Service	515 Colorow DR Salt Lake City, UT 84108-1248 And 1590 S 5200 West Salt Lake City,UT 84104

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective **04/15/2026**

(MONTH, DAY, YEAR)

Signed and Sealed **04/15/2026**

(MONTH, DAY, YEAR)

BioFire Diagnostics
PRINCIPAL

BY _____

TITLE

Atlantic Specialty Insurance Company
SURETY

BY _____

Doritza Mojica, ATTORNEY-IN-FACT

intact INSURANCE

Surety Bond No: 800227420

Power of Attorney

BioFire Diagnostics
Nevada State Board of Pharmacy

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Doritza Mojica**, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON D. NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2030

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 15th day of April, 2026.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

_____
Kara L.B. Barrow, Secretary

This Power of Attorney expires
January 31, 2030

Please direct bond verifications to surety@intactinsurance.com

Telephone: +1 860 278 1320
Website: wtwco.com

April 17, 2026

BIOMERIEUX INC
Attn: Sarah Mauney
100 Rodolphe Street
Durham, NC 27712

RE: **April – New Bonds (8)**
April – Riders (8)
Commission: 32.5%

We are pleased to enclose the above referenced bond you requested. This bond was executed based upon the information you provided. We urge you to check all of the information enclosed, including the Power of Attorney, signatures, dates, amounts, description, bond form and any other attachments.

Please be sure to affix the bond with the proper signature and seal.

If a premium is charged, our invoice will follow under separate cover and premium payment for this bond is due upon receipt. **Please note that the first term's premium related to any renewable obligation is considered fully earned.**

Willis Towers Watson negotiates commission rates with certain insurers on a corporate level. If the rate on your placement is lower than the negotiated rate, Willis Towers Watson may collect the difference directly from the insurer. These payments will not increase the cost of your bonds or otherwise impact your premium or rates. Details of these arrangements where there is compensation beyond the base compensation detailed in your commission schedule can be found at: https://www.wtwco.com/en-us/notices/p-c-national-commission-rates.

Thank you for the opportunity to service your surety needs. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Rhi Portillo
Rhi.Portillo@wtwco.com

Willis Towers Watson Northeast, Inc.
10 State House Square, 11th Floor
Hartford, CT 06103

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 800227420

Application/License No. _____

BioFire Diagnostics (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1001 South 4800 West, Salt Lake City, UT 84104 (Address of Applicant/Principal), as PRINCIPAL, and Atlantic Specialty Insurance Company (Surety Company), a corporation organized under the laws of the state of NY (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 605 Highway 169 North, Suite 800 , Plymouth, MN 55441 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 15, 2026 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 15th day of April, 2026.

APPLICANT/PRINCIPAL

BioFire Diagnostics
COMPANY

By: _____
Authorized Representative

SURETY

Atlantic Specialty Insurance Company



By: _____
Surety Company's Representative

Doritza Mojica, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

_____
Witness Haley Pulley

_____
Witness Makayla Alexis

Countersigned by:

_____
Nevada Resident Agent Malerie Janet Williams
Non-Resident License No.: 4156693
Posted February 20, 2020

intact INSURANCE

Surety Bond No: 800227420

Power of Attorney

BioFire Diagnostics
Nevada State Board of Pharmacy

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: _____ **Doritza Mojica** _____, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON D. NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2030

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 15th day of April, 2026

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

_____
Kara L.B. Barrow, Secretary

This Power of Attorney expires
January 31, 2030

Please direct bond verifications to [illegible]

Telephone: +1 860 278 1320
Website: wtwco.com

April 17, 2026

BIOMERIEUX INC
Attn: Sarah Mauney
100 Rodolphe Street
Durham, NC 27712

RE: **April – New Bonds (8)**
April – Riders (8)
Commission: 32.5%

We are pleased to enclose the above referenced bond you requested. This bond was executed based upon the information you provided. We urge you to check all of the information enclosed, including the Power of Attorney, signatures, dates, amounts, description, bond form and any other attachments.

Please be sure to affix the bond with the proper signature and seal.

If a premium is charged, our invoice will follow under separate cover and premium payment for this bond is due upon receipt. **Please note that the first term's premium related to any renewable obligation is considered fully earned.**

Willis Towers Watson negotiates commission rates with certain insurers on a corporate level. If the rate on your placement is lower than the negotiated rate, Willis Towers Watson may collect the difference directly from the insurer. These payments will not increase the cost of your bonds or otherwise impact your premium or rates. Details of these arrangements where there is compensation beyond the base compensation detailed in your commission schedule can be found at: https://www.wtwco.com/en-us/notices/p-c-national-commission-rates.

Thank you for the opportunity to service your surety needs. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Rhi Portillo
Rhi.Portillo@wtwco.com

Willis Towers Watson Northeast, Inc.
10 State House Square, 11th Floor
Hartford, CT 06103

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG bioFire Diagnostics, LLC MDEG License # (if applicable) N/A

Physical Address 1001 S 4800 W

City Salt Lake City State UT Zip 84104

Mailing Address (if different from physical address) (Attn; Sandra Perreand c/o Mary Vomund, 595 Anglum Road

City Hazelwood State MO Zip 63042

Telephone 919-620-2000 Website www.biomerieux.com

Licensing Company Email statelicensing@biomerieux.com

Section 2: Personal Information

First Linsey Middle Last Page

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITI [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address 1001 S 4800 W

City Salt Lake City State UT Zip 84104

Telephone 919-620-2000 Email statelicensing@biomerieux.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Brigham Young University			9/2004 - 9/2009
Address	**City**	**State**	**Zip**
Brigham Young University	Provo	UT	84602
Diploma/Degree obtained, if any			
Bachelor of Arts - Humanities			

School Name			From - To (MM/YY – MM/YY)
Bountiful High School			9/2001 - 6/2004
Address	**City**	**State**	**Zip**
695 South Orchard Drive	Bountiful	UT	84010
Diploma/Degree obtained, if any			
High School Diploma			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2016 - Present	[redacted]	Holladay	UT	[redacted]
4/2013 - 9/2016		Cottonwood Heights	UT	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
BioFire Diagnostics, BioMerieux			2009 - Present	
Business Address		**City**	**State**	**Zip**
1001 S 4800 W		Salt Lake City	UT	84104
Phone	**Title**		**Number of Employed Hours**	
801-736-6354	Sr. Director, SLC Supply Chain		40+ hours / week	
Description of Duties				
Planning and scheduling manufacturing activities, oversight of materials management and logistics activities				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Linsey Page, **certify that as the MDEG Administrator for**

bioFire Diagnostics, LLC,

that I (initial that you have read and meet the following requirements):

1. LP Have a high school diploma or its equivalent;
2. LP Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. LP Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. LP Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Linsey Page
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

29 April 2026
Date

Board Use Only	Date Received: 7/15/26

LINSEY PAGE

[redacted]

EXPERIENCE

Senior Director, Site Supply Chain
BioFire Diagnostics, BioMerieux | Salt Lake City, UT — June 2023-Present

Responsible for site supply chain at the Salt Lake City site including planning and scheduling, materials management, logistics, and warehousing, and inventory management and control. Contribute to the strategic plan for the site to support manufacturing processes and distribution for products with uncertain demand and rapid growth. Collaborate with global supply chain to ensure supply of BioFire product family.

Director, Reagent Planning & Scheduling
BioFire Diagnostics, BioMerieux | Salt Lake City, UT — April 2022-June 2023

Responsible for the reagent manufacturing master production schedule to ensure adequate product availability. Contributed to the strategic plan for reagent manufacturing to support rapid product growth. Collaborated with Global Supply Chain to provide clear communication and ensure reagent supply is available. Participated as subject matter expert on product development and process improvement projects.

Associate Director, Reagent Planning & Scheduling
BioFire Diagnostics, BioMerieux | Salt Lake City, UT — 2018-April 2022

Supported the continued growth of the planning and scheduling team, adding new positions to support the growth of the FilmArray product. Participated in development of site supply chain tasks in collaboration with global supply chain and other cross-functional teams.

Scheduling Manager
BioFire Diagnostics | Salt Lake City, UT — 2015-2018

Managed the creation of a planning and scheduling team within reagent manufacturing. Hired and trained new team members to support ongoing product growth.

Training Coordinator
BioFire Diagnostics | Salt Lake City, UT — 2013-2015

Manufacturing Team Lead
BioFire Diagnostics | Salt Lake City, UT — 2012-2013

Manufacturing Technician
Idaho Technology | Salt Lake City, UT — 2009-2012

EDUCATION

Bachelor of Arts
Brigham Young University | Provo, UT — August 2009

Major: Linguistics

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler bioFire Diagnostics, LLC

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 1001 S 4800 W

City Salt Lake City State UT Zip 84104

Mailing Address (if different from physical address) (Attn; Sandra Perreand c/o Mary Vomund, 595 Anglum Road

City Hazelwood State MO Zip 63042

Telephone 801-736-6354 Website www.biomerieux.com

Licensing Company Email statelicensing@biomerieux.com

Section 2: Personal Information

First Linsey Middle NMN Last Page

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address 1001 S 4800 W

City Salt Lake City State UT Zip 84104

Telephone 801-736-6354 Email statelicensing@biomerieux.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Brigham Young University		9/2004 - 9/2009	
Address	City	State	Zip
Brigham Young University	Provo	UT	84602
Diploma/Degree obtained, if any			
Bachelor of Arts - Humanities			

School Name		From - To (MM/YY – MM/YY)	
Bountiful High School		9/2001 - 6/2004	
Address	City	State	Zip
695 South Orchard Drive	Bountiful	UT	84010
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2016 - Present	[redacted]	Holladay	UT	
4/2013 - 9/2016	[redacted]	Cottonwood Heights	UT	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
BioFire Diagnostics, BioMerieux			2009 - Present	
Business Address		City	State	Zip
1001 S 4800 W		Salt Lake City	UT	84104
Phone	Title		Number of Employed Hours	
801-736-6354	Sr. Director, SLC Supply Chain		40+ hours / week	
Description of Duties				
Planning and scheduling manufacturing activities, oversight of materials management and logistics activities				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
N/A				
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
N/A				
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

June 24, 2026
Date

I, Linsey Page, **certify that as the designated representative for**

bioFire Diagnostics, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. LP I am at least 21 years of age;
3. LP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. LP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. LP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. LP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. LP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Linsey Page
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

June 24 2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Linsey Page
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

June 24, 2026
Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Salt Lake

I, Linsey Page, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

June 24, 2026
Date

Subscribed and Sworn to before me this 24 day of June 2026

Notary Public Signature

KELLY OAKS
Notary Public - State of Utah
Comm. No. 734347
My Commission Expires on
Nov 27, 2027

(Seal)

Name
Aakanksha RAWAT
Aaron GREENBERG
Aaron JOHNSON
Aaron MERLO
Aaron VANOVER
Abdi NOOR
Abhijit BOPPANA
Aboudoulaye ABOUGA
Ada HERNANDEZ
Adam ARMSTRONG
Adam FREEMAN
Adam MEJIA
Adam NELSON
Adam NGUYEN
Adam PICKRELL
Adam PRICE
Adan NAVA
Adan VARGAS-LOZANO
Addison NIELSEN
Adel IMANBEKOVA
Adela RODRIGUEZ
Adonia MARTINEZ
Adriana ZAVALA
Adriel DE JESUS AMBROSIO
Adrienna MIRANDA
Adrienne ROLLER
Aida WEBB
Aimable KAYIRANGA
Aimee RAMYA
Akissi KOUASSI
Alaimanongi PULU
Alain Bruno OUADJA KAMGA
Alaric WELSH
Albert EGBE
Albert LOBATO
Alden SWALLOW
Alex ERRIGO
Alexander ARCHULETTA
Alexander HERNANDEZ
Alexander OCHOA HERNANDEZ
Alexander TITUS
Alexandra DUNN
Alexandra GUTIERREZ
Alexandria WILLARDSEN

Alfonso RIVAS HUERTA
Ali TACKETT
Alicia WISE
Alireza FIROUZIFAR
Alissa TAUFER
Allen MEEK JR
Allen SALAS
Alma DE LEON
Alma HERNANDEZ
Alondra GOMEZ DE LA TORRE
Alondra SALAS BOLIVAR
Aloys OUEDRAOGO
Alphonse KALISA
Alvin SIHAPANYA
Amanda SPINDLER
Amber PENA
America EUDAVE
Ana AGUILERA RAMOS
Ana RODRIGUEZ GARCIA
Ana ROSAS CALLEJAS
Ana VAKAPUNA
Ana WOLFGRAMM
Anakaren HINOJOSA BATALLA
Anas ABDULRAHMAN
Andrea DOMINGUEZ AGUILAR
Andrea MARTINEZ
Andrea SMITH
Andrea TAYLOR
Andres CARRASQUILLO
Andrew ANDERSON
Andrew ANDERSON JR
Andrew GARVOILLE
Andrew KIRK
Andrew LOPEZ
Andrew LOSEE
Andrew LOVE
Andrew MURPHY
Andrew TSE
Andrew WRIGHT
Andreza CABRINI
Angel ARGUETA
Angel ISAIS
Angel OROZCO
Angela WAGGONER
Angelica GONZALEZ

Angelita BEGAYE
Angelo LECAROS
Angham EL SAFADI
Angie MORALES
Anna RUBIO
Anthony BERCEAU
Anthony HERNANDEZ
Anthony NELSON
Antonia CORONA
Antonio SACCO
April CAMARILLO
Apryl PAREDES
Arely ALVARADO DE PLEITEZ
Ariana PONCE
Arias DAVIS
Armel TUYISHIME
Arthur BULL
Arvin PASUMBAL
Ashlee NELSON
Ashley HORSTMEIER
Ashley MENDOZA CASTILLO
Ashley NICHOLS
Ashley NIELSON
Ashley OLVERA
Ashlie MALAY
Ashlynn MILLAR
Ashton SWANSON
Atcharee KONGAO
Athanase KAMAYIRESE
Athena WALKER
Audrey SIMPER
Aurora SEVILLA GONGORA
Aurore UWAMARIYA
Austin BROADBENT
Austin BROWN
Austin FARRALL
Austin GLOVER
Austin PETERSON
Autumn METZ
Ava GOLAFSHANI
Avrielle JENSEN
Azucena RAMIREZ
Azucena RIOS VALADEZ
Bailey SMITH
Barbara HECKE

Beatriz RODRIGUEZ
Benjamin CORRALES
Benjamin DUNN
Benjamin DURRANT
Benjamin GRANDLIC
Benjamin RICKETTS
Bertha ROJAS-MENDOZA
Betty LOZANO
Beyanira MENDOZA FLORES
Bhagawan KATWAL
Bishnu KHAPANGI
Blake DINSDALE
Blandine INGABIRE
Bobbie CORDOVA
Bogdan BALASA
Braden WEGESSER
Bradley MIMS
Braedan WOOD
Brandon BOWMAN
Brandon FLORENCE
Brandon HUFF
Brandon MEZA GUTIERREZ
Brandon SCHULER
Brandy FORTNEY
Breanna GALINDO
Breannia LALAMA
Brenda MATA
Brenda MITCHELL
Brendon MONTGOMERY
Brennan LARSEN
Brett CHRISTENSEN
Brett STEVENS
Brian DOYLE
Brian LOWE
Brian SHELLEY
Brian STAUFFER
Briana VELASQUEZ
Britney CURTIS
Brittnee BINGHAM
Brooke HADLEY
Bruna BECK
Bryan FULLMER
Bryan MARTINEZ ESPINO
Bryan RAMOS
Bryant HOLLAND

Calvin FLORES
Cameron PALMER
Cameron TINAO
Camille SERENI
Candy CRITCHLEY
Candy DURON LOERA
Carla GRANDE
Carla MANRIQUE CUADROS
Carla VILLENAS ROMERO
Carlos GUTIERREZ
Carlos GUZMAN
Carlos ORDONEZ VELOZ
Carlos QUIJANO
Carmen NEGRETE LOPEZ
Carmen PEREZ DE ALVAREZ
Carol WINKLER
Carolina BRIONES
Carolyn WADA
Casey MONROE
Cassandra DWORNICZEK
Cassie YOCOM
Catherine RAMIREZ
Cecilia PONCE
Cesar COLIN
Cesar GARCIA
Chantelle KADLEC
Charles BOAMAH
Charles FREDRICKSON
Charlotte RUGG
Chase ROBERTS
Chau TRAN
Chaudhry MASOOD
Cheri OTTESEN
Cheyenne MONSON
Christian MAESTAS
Christian TYSON
Christian YEPEZ
Christina ETUALE
Christina SIGRAH
Christina VINZANT
Christine BOAS
Christopher AGAR
Christopher BAXTER
Christopher BREEDON
Christopher DARNELL

Christopher MCKNIGHT
Christopher MURILLO
Christopher NGUYEN
Christopher ORME
Christopher SEPPIE
Christopher WATTS
Chuck ROBINSON
Chue YANG
Ciara CARRILLO
Ciara LADION
Cindy HERNANDEZ
Cinthia HERNANDEZ
Citlalli MARQUEZ
Clarissa BROWN
Claudia DOMINGUEZ
Claudia HILL
Claudia VELASQUEZ
Clayton BROWN
Clint THOMPSON
Cody LUCERO
Cody MENDENHALL
Cody SHEPPICK
Colby AOKI
Colby LETO
Colin ROMMEL
Conner BRATTON
Consepcion AGUIRRE CHAVEZ
Corbyn MEJIA
Corey CLARK
Cory SHUNK
Courtney STREETER
Craig THORNE
Cristela MUNOZ
Cristian PEREZ
Crystal ALCARAZ
Curtis ELDREDGE
Cyndee KER
Dah TOE
Dai DANG
Daichi ITO
Dakota WARNER
Dalia ORDONEZ
Dallas GOLDEN
Dalton HAWK
Damein RASABOUT

Damian KETCHAM
Daniel ALO
Daniel BARNHURST
Daniel CANDLAND
Daniel CUNNINGHAM
Daniel HERNANDEZ-LEON
Daniel PERRY
Daniel PUNZO
Daniel SALAZAR
Daniel WILSON
Danielle AMANN-MOHL
Dannee HERNANDEZ
Darren KENNEY
Dary BUTH
Dat LE
David BROWN
David DENG
David DUKE
David KILPATRICK
David LECAROS
David MAAFALA
David MARENCO AVILES
David OGDEN
David RANKIN
David WRIGHT
Debbie TUCSON
Deborah ZELAYA
Dejonae HOWARD
Delaney SIERRA QUINTERO
Denisse ZAMBRANO VELAZQUEZ
Derek GALLEGOS
Derek ROWELL
Devin ARMSTRONG
Devin ORTIZ
Devin PARKINSON
Deymor CHACON
Dhiraj MANGAR
Diana GARCIA GONZALEZ
Diana ROZO CRUZ
Diana TURCIOS
Diego RAMOS
Dillon MCCAULEY
Dillon RICKETTS
Dillon YOUNG
Dipa GURUNG

Dominic HUNTER
Don SJOBLOM
Donald Peter SEBUHARARA
Donaldo CORREA
Donna JAKEO
Donna URBINA
Doris ALVAREZ
Douglas ANJEWIERDEN
Douglas NELSON
Douglas WILKES
Dreena HERRON
Duc MAI
Dulce BARRANCO
Dushime NYIRANEZA
Dustin PETERSEN
Dustin ROBINSON
Dylan METCALF
Dyra CHHIN
Eddie AVALOS
Edenneil James BALATBAT
Edith CRUZ
Edith ZAPATA LOPEZ
Edmond BOGUE
Edmund SCHOLLE
Eduardo GAUSIN
Eduardo VALDIVIA
Edwin RIVERA MARTINEZ
Ekaterin DARLING
Elana TORGERSEN
Elias MATAMOROS
Elijah GOLDSBERRY
Elimar RODRIGUEZ
Elisha MIRZA
Elisha MUSINGUZI
Elizabeth DIAZ
Elizabeth GENCHIS AGUILAR
Elizabeth HANSEN
Elizabeth MUN
Elizabeth QUINTANA
Elizabeth ROSALES
Elizabeth VIRGEN
Elmay WELSH
Emely CABRERA-GARCIA
Emely MORAN-AVELAR
Emely RUJANO BRACHO

Emerson PERSCH
Emily ENRIQUEZ
Emily YELEMESSOV
Emma ERICKSON
Emma SHAPIRO
Enio JIMENEZ
Ephrem NDACYAYISENGA
Eric GAUSE
Eric KRAUTH
Eric LAST
Eric PIHUAVE
Eric SCOTT
Eric SMITH
Erica ROLLER
Erik GRIM
Erik OWEN
Erika RICHARDSON
Ermelinda TAPIA-BARRASA
Erna GASAL
Esmeralda BARRON-CONTRER
Espoir NIYONKURU
Esteban ALMARAZ REYES
Esther IKENASIO
Esther INGABIRE
Esther OTETE
Ethan GAYTON
Evan KRAMER
Evariste MURWANASHYAKA
Evelyn JAVIER
Eyvin MENDOZA
Ezequiel SILVA
Fa'ala'a SUISALA
Faagao LEFAOSEU
Faelisa ROWSELL
Fe DARLING
Fernando GARCIA
Fernando SANDOVAL RODRIGUEZ
Flor LOPEZ-INFANTE
Forrest SWEITZER
Frances LUCAS
Francine PAGE
Franck LAMBRET
Frankely RODRIGUEZ
Fritz GROOTHUIS
Fuad JEILANI

Gabriel ACEVES
Gabriel ALONSO
Gabriel DIAZ
Gabriela RODRIGUEZ
Gabriella DO NASCIMENTO JANUARIO
Gabrielle DOCTOR
Gage BRIDGES
Gage WARNER
Garry HARE
Garth NELSON
Gary HAMMOND
Genesis TAPIA GARNICA
Gentille KAMANZI
Geoffrey MCCARTY
George VAZQUEZ
Gerardo CHAVEZ
Ghafour MALEKY
Gia TA
Giancarlo DATUIN
Gilson MWANDA
Giovanni FIGUEROA
Gisela TAPIA-ANDRADE
Gisleine PAULINO
Giuliana MANRIQUE CUADROS
Glenn ELDREDGE
Gloria CARBAJAL
Gloria Tatiana FRANCO BERNAL
Gloria WALLA
Grant KRINKE
Grant MCBANE
Grant PILIMAI
Gregoria CRUZ
Gregorio NUNEZ
Gregory BONANZA
Gregory OLIVEROS
Guadalupe MACHADO
Guillermo GONZALEZ
Guiomara IRVIN
Guy SAWADOGO
Halaevalu KEFU
Halie HEMENWAY
Hamilton BODE
Hanan HUSSAIN
Hanis TASEVAC
Harley DAVIDSON

Heather HANCOCK
Heather MCGIRK
Heather WALTERS
Heidi BROWNING
Heidi ZARAGOZA LOPEZ
Helenita RUPLE
Hipolita BARRERA-CORTES
Holden KIMBLE
Hollie HOCHHAUS
Holly POTTER
Holly TY
Houryeh SADEGHZADEH
Hunter GVOZDICH
Hyunjoo CAMPA
Ian WILLIAMS
Iese KOTOWSKI
Imelda SANCHEZ
Ingrid VANG
Innocent NODJINDOROUM
Inseon JIN
Irma LARA GARCIA
Irma QUINONES
Irma TERAN
Irwin GEAUTHREAUX
Isaac MCGEE
Isabel CASTRO
Isabella GRAY
Isabelle BECERRIL
Isaiah HERNANDEZ
Isaiah VEA
Ishrat ZARIN
Isiah CAPUNAY
Isis MANSILLA
Italia AIONO
Itzel ESPITIA
Ivan NGUYEN
Ivan PEREZ
Ivette SERRANO
Ivonne LOGAH
Ivy Karen MAGDAY
Ivylyn HIPOLITO
Izabelle MORENO
J'Lynn INGLEBY
Jack ROMAN ASTUHUAMAN
Jackie JAGOLINO

Jackson TUYISENGE
Jacob ADAMS
Jacob ALLAN
Jacob CHRISTENSEN
Jacob CROOKS
Jacob ECKMAN
Jacob GORHAM
Jacob SCHROEDER
Jacob THALLER
Jacob WINTER
Jacqueline UFITABE
Jahred BAHR
Jaime ARGUETA
Jaime LOPEZ
Jaimie DIVIS
Jake HERNDON
Jakob CRAWFORD
James ALLDREDGE
James ALLEN
James BYIRINGIRO
James COLEMAN
James HACKWORTH
James KAUFMAN
James MARTINEZ
Jamie PARKER
Jana POE
Janaki Prasad Santosh KOLIPAKA
Jane BURDEN
Janet ALCARAZ
Janet ARIKIPO
Janet SANDOVAL
Janice SEUMANU
Janine UMURISA
Jano FARAH
Jared LOREDO
Jared PEREZ
Jarrod MARX
Jasher PARCO
Jasmine CERVANTES
Jasmine HARWOOD
Jasmine XAYASO
Jasminka YOLDIC
Jason ALVARADO
Jason CARTER
Jason CLEMENT

Jason CORNELIUS
Jason FLATT
Jason HARKER
Jason POTTER
Jason TRAN
Javier CASILLAS
Javier CONTRERAS
Javier FRANCO
Javier HENRIQUEZ
Jaxon ORAM
Jeanette CONTRERAS
Jeanne TUYIZERE
Jeef MBAYO
Jeffery BECKMANN
Jeffrey COSSEY
Jeffrey HUNT
Jennie CHHUN
Jennifer BEGAY
Jennifer SMITH
Jenny NGUYEN
Jeremiah LEE
Jeremy ATKINSON
Jeremy SCHWINCK
Jeremy SHARP
Jerry HOLLAND
Jerry MANNING
Jesika GALLARDO-GONZALEZ
Jesse JOHNSON
Jesse LOWRY
Jesse MUNOZ
Jesse PRAUSE
Jesse SALAZAR
Jessica INGER
Jessica RUBIO
Jessica URCINO
Jesus GUILLEN
Jeucey NEGRETE-GARCIA
Jinky MEDRANO
Joe RAJSAVONG
Joel BELL
John REES
John SCHUG
John ZWIERZCHOWSKI
Johnathan HEALY
Johnny LIRIANO

Joka DRAGICEVIC
Jonah PETIT
Jonathan DEL TORO
Jonathan KLIMAS
Jonathan PERKINS
Jonathan TAPIA
Jonathan ZAMORA
Jordan ALLEN
Jordan WILLIAMS
Jorge GRANDE
Jorge PARDO DIAZ
Jose ARAUJO-MAZO
Jose Edgardo MATA BOLANOS
Jose GALANG
Jose MALDONADO ARTEAGA
Jose MUNOZ
Jose RODRIGUEZ
Jose SOLORZANO
Jose VASQUEZ
Josefina MATA
Joselin GUTIERREZ
Joseph BLAKE
Joseph DAVIS MOLINA
Joseph GARBER
Joseph MAINS
Joseph RUGABISHA
Joshua DEMILLE
Joshua DIX
Joshua FREY
Joshua ILDEFONSO
Joshua JOHNSTON
Joshua MENDOZA FLORES
Joshua NISTLER
Joshua POPE
Joshua ROGOFF
Josianne PETIT
Josue ALVAREZ
Juan BLANCO DIAZ
Juan CASTRO
Juan SEPULVEDA
Juana RENDEROS
Judith PALENCIA
Julia MENDOZA HOVET
Julia TRAN
Julian KARMALA

Juliana MENDOZA
Julie WINROW
Julio GONZALEZ
Julius CHARLES
Junot ITEMA
Junpei CAPULONG
Justin DEVER
Justin FAWSON
Justin HOLT
Justin MUHIRWA
Justin VINEYARD
Justine NIYIBIZI
Kaden SHAW
Kadin BOMBELA
Kailani UHILA
Kalesita MAFI
Kamille PAYNE
Karen SOLORIO
Karina GRANILLO
Karina MAGANA
Karina RAMOS CONTRERAS
Karisma HERNANDEZ
Karla ALARCON CUADROS
Karla MACIAS
Karla TRUJILLO
Karson LIDDELL
Katarina MOUNTZ
Kate GRANDE
Katherine GARAY
Katherine GAUTHIER
Katherine MAREK
Katherine WRIGHT
Katherine ZAPANA
Kathleen LOPEZ
Kathryn DENISON
Kathryn SMITH-GISH
Kathy GREENBERG
Katie KARMALA
Katy NGUYEN
Kauika TAUFA
Kayllya DARR
Kealii CORNELIUS
Keely MCLURE
Keith CALL
Kelen JORMEIA

Kelia IHA
Kelly SWENSEN
Kelsey RUELAS
Kenneth GARCIA
Kenneth HART
Kenneth MYERS
Kenneth TUTTLE
Kenneth WARFIELD
Kennidy CHATTERTON
Kenny DOPORTO
Kenny TAYLOR
Keoki AIU
Ketziah SOTELO
Keven OLGUIN GOMEZ
Kevin ALVAREZ
Kevin BARNES
Kevin CRUZ
Kevin GORDON
Kevin GOSNELL
Kevin GYGI
Kevin KLEBS
Kevin KOONCE
Kevin PEREZ
Kevin PERKINS
Kevin RODRIGUEZ
Kevin STRONG
Khamsy KEOVILAYPHONE
Khloe MAHINA
Khoa DUONG
Khue TRAN
Khyler SILIM
Kien KROON
Kiera MCNELIS
Kimberley BAKER
Kimberly DELGADO ORTIZ
Kimberly MALAGAMALII
Kimberly RAMIREZ
Kimberly SORIA SIERRA
Kimberlynn IRON CLOUD
Kinneah HARRISON
Kitiara WEAVER
Kitiona KITIONA
Kjell TRETTEWICK
Kody SANSLOW
Kolotita LATU

Kristina COOK
Kulvir KAUR
Kurtis CASTELLANOS
Kyle ASHMENT
Kyle HARDY
Kyle HODGSON
Kyle QUINNEY
Kyle WHITE
Kyndra BIRCH
L SCHAUERHAMER
LaAnna BALDWIN
Laisa PENA
Lakisha LOYA
Laly OCHOA
Lance EHLERS
Landon CABRERA
Landon PARKS
Landon POAGUE
Laura HIGH
Lauren GREEN
Lauryn LOPEZ
Lavinia HAUNGA
Lawrence WINTER
Lawrence ZANGAR
LeAnn HILL
Leandro SOLANO PEDRIQUE
Lee TA
Leigh PEARSON
Leme XAYTHAVONE
Leon TRAN
Leon WYATT
Leonard GRAVEN
Lesli SAUCEDO ECHEVERRIA
Leslie EWOOL
Leslie RAMIREZ
Leslie VAN AEL
Levi CUEVAS
Levi KLEBS
Levi MOSS
Liberte NADJITEL
Lilia BIRCH
Liliana HERNANDEZ CURIEL
Liliana TORRES
Liliane MATAMEZA
Liliane UMULISA

Lily LEALAITAFEA
Linda GALLARDO
Lindsey CUTLER
Linsey PAGE
Long NGO
Loni SMITH
Lonnie ERNST
Lotiola AHOLELEI
Louis ROMAN
Lucia AKON
Luis AGUIRRE
Luis ALVAREZ
Luis ARCE-ROSALES
Luis MEDINA-URIAS
Luis OLIVERA-BERDEJO
Luis PALMAR VILLALOBOS
Luisa MAYSHO
Lupe AUTAGAVAIA
Luz AVILES
Lydia HERRERA
Lynda MACKAY
Lyndsey DE SALVO
Lyric BUCHANAN
Ma Theresa EWING
Macrina GALLARDO
Madilyn EREKSON
Madison PATCH
Maicy VUE
Makena FAKATOU
Mallory DRAEGER
Manase WURIAM
Manuel HERRERA
Manuel VELEZ
Marc BONILLA
Marc MEJIA
Marc PEHKONEN
Marcela SOUTHAM
Marcelina JIMENEZ MARTINEZ
Marco TURPIN
Mare OJULU
Margaret TAGGART
Maria ABURTO
Maria ALONZO
Maria AMAYA
Maria AMBROSE

Maria BRAVO
Maria BRITO
Maria CABRERA DE MANCILLA
Maria CONTRERAS
Maria CORONA ANGUIANO
Maria HERNANDEZ
Maria HERNANDEZ LOPEZ
Maria KAMOTO
Maria LOPEZ
Maria LOPEZ DE MEDEL
Maria MALDONADO
Maria NAVA
Maria REYES
Maria ROSAS
Maria SAUCEDO
Maria TAPIA
Maria URTECHO
Mariana MAGANA
Maribel CALDERON
Maribel GALLARDO
Marie Rose UMURAZA
Mariela PEACOCK
Marika XYDES
Mario MEZA
Marisol AGUIRRE
Marissa VALDEZ
Mark BURNETT
Mark MOODY
Mark MYERS
Mark WALTON
Mark WILLIAMS
Martin BOKANGA
Martin SMITH
Mary GARDNER
Mary LEMI
Mary TONGI
Masoud FIROUZIFAR
Mathew GARDNER
Mathew GIBBS
Mathew TURPIN
Matthew BRINGHURST
Matthew CALDERWOOD
Matthew CANAVAN
Matthew GROVER
Matthew MCARDLE

Matthew MCDONALD
Matthew PETTIS
Matthew PHILLIPS
Matthew PUTNAM
Matthew SCHOLL
Matthew SCOTT
Matthew VAGAI
Matthew YOUNGBERG
Mayra FLORES REAL
Mayte VASQUEZ SEGOVIA
Mckell BIBIAN
Meijuan HUANG
Melinda NGUY
Melissa BUCKLEY
Melissa ROMO
Meliza MENDEZ
Melvin MEDINA
Michael ANDERSON
Michael GRUENHAGEN
Michael KAMADA
Michael KITAVEELAIH
Michael KOCHEVAR
Michael REYES
Michael SABEY
Michael SAENA
Michael SMALLEY
Michael TRAN
Michael VALENZUELA
Michaela SIVERTSEN
Michel IRYAMUKURU
Michele ROCKWELL
Michelle BECERRIL
Michelle INMAN
Michelle PEREZ
Michelle USOD
Miguel LOSACCO
Milagro VILLALOBOS MARTINEZ
Milly KAYITESI
Milton MILLER
Minerva SOLIS
Miranda INMAN
Miriam LOPEZ GARCIA
Mitzi GENCHIS
Mohamed Lamine KTIR
Moise MOTHERSIL

Molly CANTWELL
Monica ARABE
Monica DELGADO
Monica DURAN
Monica MOLINA
Monica PALACIOS
Monica SIMON
Monica SPORL
Monika WAGANER
Monserrat REYES
Montserrat MENDOZA
Mor YANG
Morgynn HALL
Muhoza FREDDY
Mutwaza NDANYUZWE
My KIM
Nadiia SERHIIENKO
Nala ALEXANDER
Nancy JIMENEZ
Nancy ROBISON
Nanise TOAFE
Narron PLOYNGAM
Natalia ACEVEDO-DOMINGUEZ
Natalie CARTER
Nathan GIBBONS
Nathan HILL
Nathan MORENO
Nathan SHYAKA
Nayeli HUERTA
Nayeli OCAMPO
Nery CABALLERO-LOPEZ
Nevaeh WAGANER
Nga NGUYEN
Nicarlos FFRENCH
Nichol RUSHTON
Nicholas CHEA
Nicholas REYNOLDS
Nicholas RILEY
Nichole GARCIA
Nicole BARBER
Nicole HAWES
Nida MASON
Nidia MEDINA
Nolan SIM
Norah VISKER

Norma FERNANDEZ
Norma GONZALEZ
Norma YEPEZ
Nuttakrit CHAROENSUK
Obinnaya AHANONU
Ochieng SILVIO
Oliver PICHARDO CHAVEZ
Olivia GARCIA
Olivia IMANISHIMWE
Olivia WOLFGRAMM
Olivier CYUBAHIRO
Olivier KAYINAMURA
Omar ALVAREZ
Oralia HEREDIA
Oscar ESCOBAR
Oscar HERNANDEZ-LEON
Oscar MUNOZ
Osiris HERNANDEZ
Pablo BALCAZAR
Pablo MOREIRA
Pacifique UWERA
Paolo MONTECLARO
Patience NYASHIMWE
Patricia LEON HUAMANI
Patrick MCCULLAGH
Patrick MUSYENENE
Patrick WHITFORD
Paul HIMLE
Paul KRUGER
Paul VUE
Paul WANG
Paula CADINA
Paula MOEUNG
Paulo SOBERON MEDRANO
Peimaneh ABEDINI
Perla HERNANDEZ
Perla LOEZA
Peter CRITCHLEY
Peter LY
Phien LAM
Phillip RINDLISBACH
Philomene SOLMEM
Phuc TRAN
Phuoc DUONG
Piper SHIPMAN

Quan DUONG
Quinton PIDGEON
Rachel SANDOVAL
Radmila MAGAZIN
Rafael PEREZ
Rajab ALI
Randhir KUMAR
Randi VASQUEZ-MARTINEZ
Ranier CAMARINES
Raquel HERMOZA ATAUSINCHI
Rasmata OUEDRAOGO-ILBOUDO
Raul HENRIQUEZ
Rebecca MENGWASSER
Redempta UMURUNGI
Regin LEON
Rehema LOUISE
Rejoice MAZENGE
Ren FAULKNER
Renny BENNETT
Reno BLACKMORE
Renzo HUAYHUA
Reusacksavanh SOUPHOMMAVONG
Reven BAKER
Reylynn PORTER
Reyna GARCIA PADILLA
Rica Eloisa CAPULONG
Ricardo ASCARZA
Ricardo RETANA
Richard ALLISON
Richard GOMEZ
Richard ROBERTSON
Ricky SANCHEZ-ROSADO
Robert CORNETT
Robert JENSEN
Robert JOHNSON
Robert JORGENSEN
Robert LAUCHNOR
Robert WALTER
Robert WOOD
Robert ZAMORA
Robey LASAT
Robin FLEMING
Rocio MONROY
Rogelio MISLA
Ronald HAYES

Ronnie KIDMAN
Rosa ALVAREZ DE CAB
Rosa MOORE
Rosa WILLCOX
Roselia FREGOSO
Rosemary BOAMAH
Rowell MAGDALUYO
Ruben LOYA
Ruben MAYORAL SEGURA
Rudy LOPEZ
Ruth NYIRAMUGISHA
Ryan DALE
Ryan IRELAND
Ryan MIMS
Ryan MORRISON
Rylee MONEY
Sabrina NDIZEYE
Sage WONG
Sahra MOHAMED
Sainabou SECKAN
Salvador YEPEZ RODRIGUEZ
Samantha JENSEN
Samantha MAAFU
Samantha SIM
Samantha TRUJILLO SANCHEZ
Sameer JOLAHA
Samra TRTANJ
Samuel GARIBAY
Samuel WRIGHT
Sara WALLACE
Sarah FUENTEZ
Sarah LAURENZ
Sarah MOORE
Sarah WINSLOW
Sarjana MANGAR
Satit KONGAO
Saul FERIA
Savan METZ
Sayed Abdulmalik NEMATI
Scott BUCKLEY
Scott MALONE
Scott PETERSON
Scott QUINONEZ
Sean HARRIS
Sean NEYRA

Sean WORSHAM
Semanjah JAMES
Seren SCHUHART
Seth HAMPTON
Seth WOODHOUSE
Shahid RUSTAM
Shak QUADER
Shandeen KILLS-IN-SIGHT
Shannon BLAZEK
Shannon BURK
Shantel LEAVITT
Shari BRIGHT
Sharon PIERCE
Sharon ZHU
Shaun MICKELSEN
Shawn MICKELSEN
Shawn POLLOCK
Shayla VANWAGENEN
Shaylee EARL
Shayleen TOLI
Shelby CAB-ALVAREZ
Shelley CHOU
Shiva BASEL
Sidhant MOHANTY
Silvia AVILES
Silvia LOPEZ DE ALCARAZ
Silviano MUNOZ
Silvija IVANIC
Simona LEMUS GASCA
Siulolovao TUHA
Skyler MORGAN
Smack NTAKIYIMANA
Sofia Misaki CAPULONG
Solomona SUISALA
Son LUONG
Sonia MIRZA
Sophea SORM
Souksanh DUANGKAISONE
Spencer BUEHNER
Spencer JIN
Spencer WOLFORD
Staciann POTTER
Stack VU
Steady TSHIBELU
Stefan COLES

Stephanie HOUTZ
Stephen BRODERICK
Stephen STANKO
Sterling PERCIVAL
Steve MOORE
Steve YANEZ
Steven DENTONE
Steven HAMMER
Steven LICHFIELD
Steven NIELSEN
Stipe BODILY
Stuart DOUGLAS
Sue LARSEN
Summit VA
Sunday BACH
Sunita GURUNG
Susan KAZERANI
Susana PINA BANUELOS
Susanne OPRA
Sustika MANGAR
Tai CHRYSOSTOM
Talishia WILLIAMS
Talmage LONG
Tamara GARZA
Tammie BROWN
Tan PHAM
Tanisha SZUKALA
Tanner ANDERSON
Tara KIRTON
Taverly BUNKER
Tawnya MCKISSEN
Taylar WILLIAMS
Tayler DOYING
Taylor CHRISTENSEN
Taylor FRENCHWOOD-LARSEN
Teddy SISON
Teina RAJSAVONG
Telaya GAUDETTE
Tenzin KHANGSAR
Tenzin NGAWANG
Teodora DOMINGUEZ
Tera MILLER
Teresa MERINO
Teresa PETTY
Thao NGUYEN

Theara CHHIM
Thearith CHHIM
Thearom CHHIM
Thirtha SUBBA
Thomas BALLARD
Thomas BODILY
Thomas TOLMAN
Thongsouk THAKHAMPHOU
Thor ROGERS
Thrassilla KHOKHAR
Thuy NGUYEN
Tibila Issaka SIMPORE
Tiffany GARCIA PROWS
Tiffany RIDDLE
Timothy BARBER
Timothy BORSOS
Timothy HONGSYVILAY
Timothy LANE
Timothy VANKRALINGEN
Tina BARBOZA-FLORES
Tina MAY
Tina NGO
Tiotala LEIATAUA
Tirhas HABTOM
Tirso PENA GONZALEZ
Toby SHELDON
Todd BROUGH
Todd LINDQUIST
Tony CYIZANYE
Tracy DO
Tracy OJO
Trang NGUYEN
Trang NGUYEN
Travis BUCKLEY
Travis HALL
Trenton BYTHEWAY
Trenton HARRIS
Trevor RINGWOOD
Trevor TURPIN
Troy KETTERLING
Troy TONNESEN
Trustyn MAINS
Tuitui MAPU
Tuong DINH
Tyler DAVIS

Tyler FARRELL
Tyler GUERRICABEITIA
Tyler HANCOCK
Tyler KARREN
Tyler MOORE
Tyler NICHOLSON
Tyler SAMPSON
Tyson DRAPER
Tyson MOORE
Umulisa CHANTAL
Unique RAI
Vaiotama AIVALE
Valentina NOCKAI
Valerie SUAREZ UTRILLA
Vanessa GALLARDO
Vanessa PAINTER
Vanessa RONDAS
Vanessa RUIZ RIVERA
Veronica NEGRON
Veronica VILLEGAS
Vicmar ROJAS PAZ
Victor FERNANDEZ
Vincent MURRAY
Von MALICHANH
Vu NGUYEN
Wal WEI
Wataru CAPULONG
Wattana CHAISOONTORNYOTIN
Wendy FUENTES
Wendy PHELPS
Wesley CHAN
Wesley GARLICK
Weston GILLESPIE
Whitney BRAMBILA
Whitney HOUSTON
William LEWIS
William RAMOS
William SIKORSKI
William SWAIN
Willy SERUGO
Wolfe KELLY
Xinmeng ZHANG
Xuexian LI
Yadira HERNANDEZ CARDENAS
Yamil ARZABA SERRANO

Yamilet FREGOSO
Yanet JIMENEZ
Ye LIU
Yevhenii BEZUHLYI
Yujeyry JIMENEZ
Yuli FEI
Yves TUYISENGE
Yvonne BAMURANGE
Yvonne VILCHIS
Zachariah BURNETT
Zachary BURTON
Zachary HUBBARD
Zachary JUAREZ
Zachary METZGER
Zachary TAYLOR
Zahia IBRAHIM
Zeljko PASALIC
Zeljko PEHAR
Zuleyma MONTES
Zusette BROWN
Zyrelle CO

4S

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10) ■ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10)

Section 1: General Information

Facility Name: Blue Heron Pharmaceuticals LLC

Physical Address: 5727 Missouri Ave Ste 207

City: New Port Richey State: FL Zip: 34652

Mailing Address (if different from physical address): PO Box 50610

City: Mesa State: AZ Zip: 85208

Telephone: 813-380-0271 Website: www.blueheronpharma.com

Name of Designated Representative (DR): William Webster

Licensing Company Email: jblayter@blueheronpharma.com DR Email: wwebster@blueheronpharma.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies ☐ Practitioners ☐ Hospitals ■ Wholesalers ☐ Veterinarians ☐ Others:	■ Dangerous Drugs ☐ Controlled Substances ☐ [a]Medical Products (medical devices, equipment, supplies, gases) ■ Others: OTC, dietary suppliments	■ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ☐ Others:

Section 2: ONLY COMPLETE THIS SECTION IF THE COMPANY IS WHOLESALING "Medical Products (medical devices, equipment, supplies and gases). Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 3 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 4: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Axia Medical Solutions LLC
Address: 10691 King Williams Dr City: Dallas State: TX Zip: 75220
Name: Legacy Health US LLC
Address: 255 Hudson St City: Hackensack State: NJ Zip: 07601
Name: Matrix Distributors
Address: 410-450 North Avenue East City: Cranford State: NJ Zip: 07016
Name: Real Value Products Corporation
Address: 5100 Commerce Parkway City: San Antonio State: TX Zip: 78218

Section 5: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida
Parent Company (if any): Nine Star Holdings LLC
Corporation/Organization Name:
Mailing Address: 1760 E Pecos Rd Ste 332
City: Gilbert State: AZ Zip: 85295
Telephone: 813-380-0271 Email:
Contact Person Name: Amber Edmunds

Section 7: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 8: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 9: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 10: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✔" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✔	✔		
• **List the top four corporation shareholders and their percent ownership.**	✔			
• **List of all corporation shareholders and their percent ownership.**		✔		
• **List of all partners and their percent ownership.**			✔	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✔	✔	✔	✔
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✔	✔	✔
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✔	✔	✔
• **Copy of DEA certificate if handling controlled substances**	✔	✔	✔	✔
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✔			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✔	✔	✔	✔
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✔	✔	✔	✔
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale [a]Medical Products (medical devices, equipment, supplies, gases). (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✔	✔	✔	✔
• **If providing [a]Medical Products (medical devices, equipment, supplies, gases), supply a copy of proof of insurance (NAC 639.6957).** The Medical Products wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✔	✔	✔	✔
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 9)				
• **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20NRS%20639.500%20-%20Effective%2001.07.2026%20-%20Wholesaler%20-%20Post%20on%201.26.26.pdf.		✔	✔	✔
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✔	✔	✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Blue Heron Pharmaceuticals LLC

Facility Name

Joanna Blayter

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

8/21/26

Date

Board Use Only	Date Received: 9/9/26	Amount: $1600 ck 1008

Blue Heron
PHARMACEUTICALS

Officer Information

Name: Amber Edmunds
Title: Operations Manager
Address: [redacted]
Phone N[redacted]
Email: orders@blueheronpharma.com
DOB: [redacted]
Last 4 [redacted]

Name: William Webster
Title: Manager/ Designated Representative
Address: [redacted]
Phone N[redacted]
Email: wwebster@blueheronpharma.com
DOB: [redacted]
Last 4 [redacted]

Name: Brett Bryant
Title: Sales Manager
Address: [redacted]
Phone N[redacted]
Email: sales@blueheronpharma.com
DOB: [redacted]
SSN [redacted]

Blue Heron Pharmaceuticals LLC, whose Manager is William Webster, is wholly owned by Nine Star Holdings LLC.

State of Florida
Department of State

I certify from the records of this office that BLUE HERON PHARMACEUTICALS LLC is a limited liability company organized under the laws of the State of Florida, filed on February 27, 2025.

The document number of this limited liability company is L25000101204.

I further certify that said limited liability company has paid all fees due this office through December 31, 2026, that its most recent annual report was filed on June 16, 2026, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Sixteenth day of June, 2026

Secretary of State

Tracking Number: 6905653046CC

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

Ron DeSantis, Governor

Melanie S. Griffin, Secretary

Florida dbpr

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

FLORIDA DRUGS, DEVICES AND COSMETICS

THE Prescription Drug Manufacturer - Virtual HEREIN HAS REGISTERED UNDER THE PROVISIONS OF CHAPTER 499, FLORIDA STATUTES

BLUE HERON PHARMACEUTICALS LLC

5727 MISSOURI AVE
SUITE 207
NEW PORT RICHEY FL 34652

LICENSE NUMBER: 4545

EXPIRATION DATE: AUGUST 31, 2027

Always verify licenses online at MyFloridaLicense.com

ISSUED: 07/30/2026

Do not alter this document in any form.

This is your license. It is unlawful for anyone other than the licensee to use this document.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. B150106802

Application/License No. _____

Blue Heron Pharmaceuticals LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5727 Missouri Ave St, Suite 207, New Port Richey, FL 34652 (Address of Applicant/Principal), as PRINCIPAL, and Old Republic Surety Company (Surety Company), a corporation organized under the laws of the state of Wisconsin (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 18500 W Corporate Dr, Ste 170, Brookfield, WI 53045 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 9/4/2026 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Pac West Pharmaceuticals

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 4th day of September, 20 26.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

Dana K Benson, Attorney-in-fact
print name

SEAL

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

OLD REPUBLIC SURETY COMPANY

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That OLD REPUBLIC SURETY COMPANY, a Wisconsin stock insurance corporation, does make, constitute and appoint:

Dana K Benson Of CEDAR CITY, Utah

its true and lawful Attorney(s)-in-Fact, with full power and authority, not exceeding $10,000,000, for and on behalf of the company as surety, to execute and deliver and affix the seal of the company thereto (if a seal is required), bonds, undertakings, recognizances or other written obligations in the nature thereof, ***(other than bail bonds, bank depository bonds, mortgage deficiency bonds, mortgage guaranty bonds, guarantees of installment paper and note guaranty bonds, self-insurance workers compensation bonds guaranteeing payment of benefits, waste management bonds, hazardous waste remediation bonds or black lung bonds),*** as follows:

Effective Date: 09/04/2026

Bond Number: B150106802	Bond Amount:	Twenty-Five Thousand Dollars	$ 25,000.00
Principal Name:	Blue Heron Pharmaceuticals LLC		
Obligee Name:	NV State Board of Pharmacy, Nevada		

and to bind OLD REPUBLIC SURETY COMPANY thereby, and all of the acts of said Attorneys-in-Fact, pursuant to these presents, are ratified and confirmed. This appointment is made under and by authority of the board of directors at a special meeting held on February 18, 1982.

This Power of Attorney is signed and sealed by facsimile under and by the authority of the following resolutions adopted by the board of directors of the OLD REPUBLIC SURETY COMPANY on February 18,1982.

RESOLVED that the president, any vice president or assistant vice president, in conjunction with the secretary or any assistant secretary, may appoint attorneys-in-fact or agents with authority as defined or limited in the instrument evidencing the appointment in each case, for and on behalf of the company to execute and deliver and affix the seal of the company to bonds, undertakings, recognizances, and suretyship obligations of all kinds; and said officers may remove any such attorney-in-fact or agent and revoke any Power of Attorney previously granted to such person.

RESOLVED FURTHER that any bond, undertaking, recognizance, or suretyship obligation shall be valid and binding upon the Company

(i) when signed by the president, any vice president or assistant vice president, and attested and sealed (if a seal be required) by any secretary or assistant secretary; or

(ii) when signed by the president, any vice president or assistant vice president, secretary or assistant secretary, and countersigned and sealed (if a seal be required) by a duly authorized attorney-in-fact or agent; or

(iii) when duly executed and sealed (if a seal be required) by one or more attorneys-in-fact or agents pursuant to and within the limits of the authority evidenced by the Power of Attorney issued by the company to such person or persons.

RESOLVED FURTHER that the signature of any authorized officer and the seal of the company may be affixed by facsimile to any Power of Attorney or certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the company; and such signature and seal when so used shall have the same force and effect as though manually affixed.

IN WITNESS WHEREOF, OLD REPUBLIC SURETY COMPANY has caused these presents to be signed by its proper officer, and its corporate seal to be affixed this 4th day of September, 2026.

OLD REPUBLIC SURETY COMPANY

Secretary

President

STATE OF WISCONSIN, COUNTY OF WAUKESHA - SS

On this 4th day of September, 2026, personally came before me, Steve R. Denault and Kevin J. Abitz, to me known to be the individuals and officers of the OLD REPUBLIC SURETY COMPANY who executed the above instrument, and they each acknowledged the execution of the same, and being by me duly sworn, did severally depose and say: that they are the said officers of the corporation aforesaid, and that the seal affixed to the above instrument is the seal of the corporation, and that said corporate seal and their signatures as such officers were duly affixed and subscribed to the said instrument by the authority of the board of directors of said corporation.

VANESSA M COLE
Notary Public
State of Wisconsin

Notary Public

My Commission Expires: 11/28/2029

(Expiration of notary's commission does not invalidate this instrument)

CERTIFICATE

I, the undersigned, assistant secretary of the OLD REPUBLIC SURETY COMPANY, a Wisconsin corporation, CERTIFY that the foregoing and attached Power of Attorney remains in full force and has not been revoked; and furthermore, that the Resolutions of the board of directors set forth in the Power of Attorney, are now in force.

0486005

Signed and sealed at the City of Brookfield, WI this 4th day of September, 2026.

Secretary

ORSC 22262 (3-06)

DIXIE LEAVITT AGENCY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Blue Heron Pharmaceuticals LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 5727 Missouri Ave Ste 207

City: New Port Richey State: FL Zip: 34652

Mailing Address (if different from physical address): PO Box 50610

City: Mesa State: AZ Zip: 85208

Telephone: 813-380-0271 Website: www.blueheronpharma.com

Licensing Company Email: Jblayter@blueheronpharma.com

Section 2: Personal Information

First: William Middle: Last: Webster

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or I[redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: New Port Richey State: FL Zip: [redacted]

Telephone: [redacted] Email: wwebster@blueheronpharma.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Jackson Memorial High School		1993-1997	
Address	City	State	Zip
101 Don Connor Blvd	Jackson Township	NJ	08527
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Ocean County College		2000-2001	
Address	City	State	Zip
1 College Dr	Toms River	NJ	08754
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/25 - current	[redacted]	New Port Richey	FL	[redacted]
09/19 - 09/25		Tampa	FL	
08/17 - 09/19		New Port Richey	FL	
07/13 - 08/17		New Port Richey	FL	
From - To (MM/YY – MM/YY)		City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Blue Heron Pharmaceuticals				From - To (MM/YY – MM/YY): 06/25 - present
Business Address: 5727 Missouri Ave. Ste # 207	City: New Port Richey		State: FL	Zip: 34652
Phone: 813-380-0271	Title: Warehouse Manager; Designated Representative		Number of Employed Hours: 2,000 +	
Description of Duties: Maintained, stored, inventory, and shipping of products within set guidelines				

Business Name: Wellgistics				From - To (MM/YY – MM/YY): 08/22 - 05/25
Business Address: 358 Eagles Landing Dr.	City: Lakeland		State: FL	Zip: 33810
Phone: 863-333-9700	Title: Warehouse Representative		Number of Employed Hours: 5,000 +	
Description of Duties: Picked and packed product. Oversaw flow of in and out product. Kept inventory and maintained cohesion btw shipping + receiving				

Business Name				From - To (MM/YY – MM/YY)
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, William Webster, **certify that as the designated representative for** Blue Heron Pharmaceuticals

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1 X I am at least 21 years of age.

3 X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.

4 X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler.

5 X I will be employed full-time in a managerial level position with the pharmacy or wholesaler.

6 X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and

7 X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

William Webster

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/18/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

William Webster

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/18/26

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pasco

I, William Webster, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/19/26

Date

Subscribed and Sworn to before me this 19th day of August.

Notary Public Signature

SEAN McMANUS
MY COMMISSION # HH 612396
EXPIRES: November 14, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Blue Heron Pharmaceuticals LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 5727 Missouri Ave Ste. 207

City: New Port Richey State: FL Zip: 34652

Mailing Address (if different from physical address): PO Box 50610

City: Mesa State: AZ Zip: 85208

Telephone: 813-380-0271 Website: www.blueheronpharma.com

Licensing Company Email: jblayter@blueheronpharma.com

Section 2: Personal Information

First: William Middle: Last: Webster

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITI: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Addr: [redacted]

City: New Port Richey State: FL Zi: [redacted]

Telephone: [redacted] Email: wwebster@blueheronpharma.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Ocean County College		2001	
Address	**City**	**State**	**Zip**
1 College Dr	Toms River	NJ	08754
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Jackson Memorial High School		1993-1997	
Address	**City**	**State**	**Zip**
101 Don Connor Blvd	Jackson Township	NJ	08527
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/25-current	[redacted]	New Port Richey	FL	[redacted]
09/19-09/25		Tampa	FL	
08/17-09/19		New Port Richey	FL	
07/13-08/17		New Port Richey	FL	
From - To (MM/YY – MM/YY)	Address	City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY - MM/YY)	
Blue Heron Pharmaceuticals			06/25 - present	
Business Address		**City**	**State**	**Zip**
5727 Missouri Ave, Ste 207		New Port Richey	FL	34652
Phone	**Title**			
813-380-0271	Warehouse Manager / Designated Representative			
Description of Duties				
Maintained, stored, inventoried, and shipped out products within set guidelines				

Business Name			From - To (MM/YY - MM/YY)	
Wellgistics			08/22 - 05/25	
Business Address		**City**	**State**	**Zip**
358 Eagles Landing Dr.		Lakeland	FL	33810
Phone	**Title**			
863-333-9700	Warehouse Representative			
Description of Duties				
Shipping, receiving, picking & packing, inventory. Oversaw storage and overall in-and-out flow of product.				

Business Name			From - To (MM/YY - MM/YY)	
Family Pharmacy			09/16 - 08/22	
Business Address		**City**	**State**	**Zip**
17510 US Hwy 41		Lutz	FL	33549
Phone	**Title**			
941-921-6645	Pharmacy Tech			
Description of Duties				
Storing, bottling & inventory of product & lab supplies Maintaining & cleaning lab and all utensils & equipment				

Business Name			From - To (MM/YY - MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY - MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

William Webster

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/31/26

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pasco

I, William Webster, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/31/26

Date

Subscribed and Sworn to before me this 31 day of Aug. 2026

Notary Public Signature

TYLER M. DANIELS
MY COMMISSION # HH 328078
EXPIRES: November 1, 2026

(Seal)

Blue Heron
PHARMACEUTICALS

List of Employees

William Webster - Manager, Designated Representative

Joanna Blayter - Licensing

Nicole Montalegne - Accounts Manager / Admin

Dustin Boyles - Director of National Accounts

4T

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: DePuy Synthes Products Inc.

Physical Address: 374 North Haverhill Road

City: West Palm Beach State: FL Zip: 33415

Mailing Address (if different from physical address): 374 North Haverhill Road

City: West Palm Beach State: FL Zip: 33415

Telephone: 561-493-8258 Website: jnjmedtech.com

Name of Designated Representative (DR): Keafta Dokes

Licensing Company Email: Kdokes@its.jnj.com DR Email: Kdokes@its.jnj.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☑ Manufacturer See Attachment A
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☑ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☑ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: The Anspach Effort, Inc.

Address: 4500 Riverside Drive City: Palm Beach Gardens State: FL Zip: 33410

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): DePuy Spine, LLC

Corporation/Organization Name: DePuy Synthes Products Inc.

Mailing Address: 374 North Haverhill Road

City: West Palm Beach State: FL Zip: 33415

Telephone: 717-598-1769 Email: Kdokes@its.jnj.com

Contact Person Name: Keafta Dokes

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		X
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

DePuy Synthes Products Inc.
Facility Name

Keafta Dokes
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

2/3/26
Date

Board Use Only	Date Received: 2.11.26	Amount: $500 ck 31091

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
DePuy Synthes West Palm Beach
374 N Haverhill Rd Ste 400
West Palm Beach, FL 33415
Registration Number: 3025110439
FEI Number*: 3025110439
Status: Active
Date Of Registration Status: 2026

Owner/Operator:
THE ANSPACH EFFORT, INC.[6]
4500 Riverside Dr
Palm Beach Gardens, FL US 33410
Owner/Operator Number: 1045834[7]

Official Correspondent:
Desiree Saracino
4500 Riverside Dr
Palm Beach Gardens, FL 33410
Phone: 862-2680924

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

---

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1045834&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1045834&OwnerOperator

Page Last Updated: 02/23/2026

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsc | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of **Health & Human Services**

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1045834&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=1045834&OwnerOperator

Attachment A

Nature of Business

DePuy Synthes Products Inc. (DePuy) is a medical device manufacturer. DePuy physically ships its own products to hospitals and veterinarians. Depuy does not physically manufacture its products on-site at its facility. As such, DePuy does not hold FDA establishment registration. Provided is the information for the physical manufacturer.

The Anspach Effort, Inc.
4500 Riverside Drive, Palm Beach Gardens, FL 33410
FDA registration #: 1045834

Attachment B

Corporation Information

Corporate Officers

David Brooks
Vice President / Head of Supply Chain Digital Surgery DPS

Sean Kelleher
Vice President/ Sr. Finance Director Orthopedics SC

Michael Walker
Treasurer / VP of Finance and Global CFO Depuy Synthes

Parent Company

DePuy Spine, LLC
325 Paramount Drive, Raynham, MA 02767
% ownership: 100

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "DEPUY SYNTHES, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TENTH DAY OF AUGUST, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL FRANCHISE TAXES HAVE BEEN ASSESSED TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

10697817 8300

SR# 20264009692

Authentication: 204775197

Date: 08-10-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

Attachment F

Regarding the Resident State License

The resident state licensing agency, the Florida Department of Business & Professional Regulation, Division of Drugs, Devices and Cosmetics (Department), does not license companies distributing medical devices in or into Florida. Enclosed is documentation from the Department.

www.myfloridalicense.com/DBPR/drugs-devices-and-cosmetics/faqs/#ddc

DIVISION OF DRUGS, DEVICES AND COSMETICS - FAQS

Drugs, Devices & Cosmetics FAQs

To obtain an interpretation of statute or rule from an agency requires the submission of a Petition for Declaratory Statement that is authorized by Chapter 120, Florida Statutes and an agency cannot provide an informal legal opinion. The responses to the frequently asked questions are not intended to be legal opinions or statements of agency policy and you are strongly encouraged to seek the guidance of a regulatory consultant to assist you regarding the interpretation and application of Florida Statutes and rules.

Definitions:

- "DBPR" or the "department" or refers to the Florida Department of Business and Professional Regulation.
- "DEA" refers to the U.S. Drug Enforcement Administration.
- "ARCOS" refers to the Automation of Reports and Consolidated Orders System operated by DEA.
- "CSR" refers to Florida's state analogue to ARCOS, the Controlled Substance Reporting system.
- "E-FORCSE (https://florida.pmpaware.net/login)" refers to Florida's "Electronic-Florida Online Reporting of Controlled Substances Evaluation", aka the "Prescription Drug Monitoring Program" or "PDMP". For more information visit the E-FORCSE homepage at https://www.floridahealth.gov/statistics-and-data/e-forcse/index.html (https://www.floridahealth.gov/statistics-and-data/e-forcse/index.html).
- "FTP" File Transfer Protocol

— Division of Drugs, Devices and Cosmetics

– Does my company need a permit?

DDC permitting requirements as regards drugs, (medical) devices and cosmetics fall into two main categories:(a) manufacturing and repackaging of drugs, medical devices and cosmetics conducted in Florida, and (b) distributing drugs, medical devices and cosmetics in and into Florida.

Activity Description	Location	Permit (Generally) Required under Chapter 499?

Manufacturing a Drug, Device or Cosmetic	In Florida	Yes
Repackaging a Drug, Device or Cosmetic	In Florida	Yes
Distributing a Prescription Drug	In or Into Florida	Yes
Distributing an Over-the-Counter Drug	In or Into Florida	No
Distributing a Device	In or Into Florida	No
Distributing a Cosmetic	In or Into Florida	No

- What is a "drug", "device", or "cosmetic"?

Refer to Section 499.003, Florida Statutes: http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0400-0499/0499/Sections/0499.003.html (http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0400-0499/0499/Sections/0499.003.html) Please note that "drug" specifically includes active pharmaceutical ingredient (API). Also, "devices" that contain "drugs" are classified as drugs if any of the principal intended purposes is achieved through chemical action.

- What is "distributing"?

Understanding this term is critical to avoid violating Chapter 499, Florida Statutes. Florida law defines "distributing" or "distribution" to implicate both physical possession and legal title or ownership. The term means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. For example, a broker of a prescription drug wholesale transaction may require a permit under Florida law. The term excludes, however, certain administrative activities.

My company distributes medical convenience kits and other "combination products" to customers in Florida. Do we need a permit?

My company's administrative office does not handle any prescription drugs. Do we still need to get a permit for that location?

My company is relocating its operation. Do we need to apply for a new permit?

My company is undergoing a change of ownership. Do we need to (re)apply?

My company is a prescription drug wholesale distributor (in-state or out-of-state). Our Certified Designated Representative (CDR) just quit. What do we do?

My company manufactures and/or distributes active pharmaceutical ingredient ("API") to customers in Florida. Do we need a permit?

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. K4206547A

Application/License No. _____

DePuy Synthes Products Inc. and
DePuy Synthes Sales Inc., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
374 North Haverhill Road, West Palm Beach, FL 33415 and 325 Paramount Drive, Raynham, MA 02767-0350 respectively, as
(Address of Applicant/Principal)
PRINCIPAL, and Federal Insurance Company, a
(Surety Company)
corporation organized under the laws of the state of Indiana
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
202B Halls Mill Road, Whitehouse Station, NJ 08889 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 5th, 2025.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 5th day of June, 2025.

APPLICANT/PRINCIPAL

COMPANY DePuy Synthes Products Inc. and DePuy Synthes Sales Inc.

Authorized Representative
John Denton, Assistant Secretary

SURETY Federal Insurance Company

Surety Company's Representative

Debra A. Deming, Attorney-in-fact
print name
and Non-Resident Agent License No. 611197, NPN: 3641688

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Sandra Diaz

Witness Anne Potter

Countersigned by:

N/A
Nevada Resident Agent

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Delaware corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint Valorie Spates and Beverly Woolford of Garden City, New York; Debra A. Deming, Sandra Diaz, Vilma Gonzalez, Peter Healy, Pablo Garcia Horcajo, Francesca Kazmierczak, Aklima Noorhassan, Anne Potter and Frances Rodriguez of New York, New York ----------

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **15th** day of **July, 2024.**

Rupert HD Swindells, Assistant Secretary

Warren Eichhorn, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss

On this 15th day of **July, 2024** before me, a Notary Public of New Jersey, personally came Rupert HD Swindells and Warren Eichhorn, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Rupert HD Swindells and Warren Eichhorn, being by me duly sworn, severally and each for himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies, and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

Albert Contursi
NOTARY PUBLIC OF NEW JERSEY
No 50202369
Commission Expires August 22, 2027

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Rupert HD Swindells, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(I) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(II) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this 5th day of June, 2025

Rupert HD Swindells, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903-3493 Fax (908) 903-3656 e-mail: surety@chubb.com

FEDERAL INSURANCE COMPANY

STATEMENT OF ASSETS, LIABILITIES AND SURPLUS TO POLICYHOLDERS

Statutory Basis

December 31, 2024

(In thousands)

ASSETS		*LIABILITIES AND SURPLUS TO POLICYHOLDERS*	
Cash, Cash Equivalents, and ST Investments	$ (355,746)	Outstanding Losses and Loss Expenses	$ 10,612,093
United States Government, State and Municipal Bonds	3,847,216	Reinsurance Payable on Losses and Expenses	1,730,804
Other Bonds	9,063,626	Unearned Premiums	3,117,855
Stocks	361,584	Ceded Reinsurance Premiums Payable	417,703
Other Invested Assets	1,562,503	Other Liabilities	583,379
TOTAL INVESTMENTS	14,479,183	TOTAL LIABILITIES	16,461,834
Investments in Affiliates:		Capital Stock	20,980
Great Northern Ins. Co.	444,946	Paid-In Surplus	2,711,474
Vigilant Ins. Co.	392,348	Unassigned Funds	2,245,956
Chubb National Ins. Co.	204,099		
Chubb Indemnity Ins. Co.	185,760	SURPLUS TO POLICYHOLDERS	4,978,410
Chubb Ins. Co. of New Jersey	41,523		
Chubb Lloyds Ins. Co. of Texas	6,140		
Other Affiliates	71,980		
Premiums Receivable	2,574,791		
Other Assets	3,039,474		
TOTAL ADMITTED ASSETS	$ 21,440,244	TOTAL LIABILITIES AND SURPLUS	$ 21,440,244

Investments are valued in accordance with requirements of the National Association of Insurance Commissioners. At December 31, 2024, investments with a carrying value of $569,829,993 were deposited with government authorities as required by law.

STATE OF PENNSYLVANIA

COUNTY OF PHILADELPHIA

John Taylor, being duly sworn, says that he is Senior Vice President of Federal Insurance Company and that to the best of his knowledge and belief the foregoing is a true and correct statement of the said Company's financial condition as of the 31 st day of December, 2024.

Sworn before me this March 20, 2025

Senior Vice President

Notary Public

August 8, 2027
My commission expires

Commonwealth of Pennsylvania - Notary Seal
Diane Wright, Notary Public
Philadelphia County
My commission expires August 8, 2027
Commission number 1235745
Member, Pennsylvania Association of Notaries

AON

June 5, 2025

Michelle Madsen on behalf of
Mary O'Hara
DEPUY SYNTHES PRODUCTS, INC. & DEPUY SYNTHES SALES INC.
374 North Haverhill Road
West Palm Beach, FL 33415

RE: NEVADA STATE BOARD OF PHARMACY
Bond #: K4206547A
Project: Pharmaceutical Wholesaler Surety Bond
Bond Amount: $100,000.00

Dear Michelle:

Enclosed please find the above captioned bond(s) executed per Mary O'Hara's request.

The bond(s) must be signed by an authorized representative of your company, witness by two and sealed with the corporate seal if applicable. Bond executed in 1 counterparts.

It is your responsibility to carefully review the bond(s) prior to execution to verify they have been presented on the correct form with the appropriate names(s), bond amounts and dates, and to ensure the bond(s) conform with your needs and instructions to us and provide the appropriate terms to all parties. Any discrepancies, deficiencies or modifications must immediately be brought to our attention, in writing. Failing such advice to us, you understand we will have no liability for any deficiencies or discrepancies in or required modifications to the bond(s).

By affixing your signature, executing and providing this bond(s) to the obligee you are verifying and, we will justifiably assume, the bond(s) has been issued correctly with the best interests and requirements of all parties being properly considered.

Sincerely,

Debra A. Deming

Debra A. Deming
Record #: 3007091

Attachment H

Certificate of Liability Insurance

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 7/29/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Marsh USA, LLC
1166 Avenue of the Americas
New York, NY 10036
Attn: newyork.certs@marsh.com - fax # 212-948-0500

CN102448867-J&Jr-GAWP-18-19

CONTACT NAME:
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : ACE American Insurance Company	22667
INSURER B :	
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
JOHNSON & JOHNSON ET AL
ONE JOHNSON & JOHNSON PLAZA
ATTN: ERIN SHERIDAN
RISK MANAGEMENT
NEW BRUNSWICK, NJ 08933

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			HDO G4937589A	03/01/2026	03/01/2027	EACH OCCURRENCE	$ 5,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 5,000,000
							MED EXP (Any one person)	$ 100,000
							PERSONAL & ADV INJURY	$ 5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 10,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ N/A
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE / OTH-ER	
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH)	N/A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

WPB
374 North Haverhill Road
West Palm Beach, FL 33415

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
of Marsh USA Inc.

Michaela Grasshoff

© 1988-2016 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG DePuy Synthes Products Inc. MDEG License # (if applicable) _____

Physical Address 374 North Haverhill Road

City West Palm Beach State FL Zip 33415

Mailing Address (if different from physical address) 374 North Haverhill Road

City West Palm Beach State FL Zip 33415

Telephone 561-493-8258 Website jnjmedtech.com

Licensing Company Email Kdokes@its.jnj.com

Section 2: Personal Information

First Keafta Dokes Middle Royaza Last Dokes

Alias(es, ni[redacted]anges, etc.) _____

Date of Bir[redacted] SSN or IT[redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 374 North Haverhill Road

City West Palm Beach State FL Zip 33415

Telephon[redacted] Email Kdokes@its.jnj.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: University of Phoenix			From - To (MM/YY – MM/YY)
Address: 4035 South Riverpoint Parkway	City: Phoenix	State: AZ	Zip: 85040
Diploma/Degree obtained, if any: Master of Business Administration			
School Name: Northern Illinois University			From - To (MM/YY – MM/YY)
Address: 1425 W. Lincoln Hwy.	City: DeKalb	State: IL	Zip: 60115
Diploma/Degree obtained, if any: BA Corporate Communications			
School Name: Homewood Flossmoor HS			From - To (MM/YY – MM/YY)
Address: 999 Kedzie Ave	City: Flossmoor	State: IL	Zip: 60422
Diploma/Degree obtained, if any: High School Diploma			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): 01/16 -Present	Address: [redacted]	City: Coral Springs	State: FL	Zip: [redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Depuy Synthes Products, Inc.			11/22 - Present	
Business Address	City	State	Zip	
374 North Haverhill Road	West Palm Beach	FL	33415	
Phone	Title	Number of Employed Hours		
815-757-7473	Senior Group Lead	Approx. 6,000 hours		
Description of Duties				
Lead and develpoy a team of frontline leads & warehouse associates accross materials management, warehouse operation and finished good distribution.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip	
Phone	Title	Number of Employed Hours		
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip	
Phone	Title	Number of Employed Hours		
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip	
Phone	Title	Number of Employed Hours		
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip	
Phone	Title	Number of Employed Hours		
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2/3/24
Date

I, Keafta Dokes, **certify that as the MDEG Administrator for**

DePuy Synthes Products Inc.,

that I (initial that you have read and meet the following requirements):

1. KRD Have a high school diploma or its equivalent;
2. KRD Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. KRD Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. KRD Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Keafta Dokes
Print Name (First, Last)

Keafta Dokes
Original Signature (electronic, copies or stamps not accepted)

2/3/26
Date

Board Use Only	Date Received: 2/13/26

Attachment D

Designated Representative Form

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler DePuy Synthes Products Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 374 North Haverhill Road

City West Palm Beach State FL Zip 33415

Mailing Address (if different from physical address) 374 North Haverhill Road

City West Palm Beach State FL Zip 33415

Telephone 561-493-8258 Website jnjmedtech.com

Licensing Company Email Kdokes@its.jnj.com

Section 2: Personal Information

First Keafta Middle Royaza Last Dokes

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 374 North Haverhill Road

City West Palm Beach State FL Zip 33415

Telephone [redacted] Email Kdokes@its.jnj.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: University of Phoenix		From - To (MM/YY – MM/YY)	
Address: 4035 South Riverpoint Parkway	City: Phoenix	State: AZ	Zip: 85040
Diploma/Degree obtained, if any: Master of Business Administration			
School Name: Northern Illinois University		From - To (MM/YY – MM/YY)	
Address: 1425 W. Lincoln Hwy.	City: DeKalb	State: IL	Zip: 60115
Diploma/Degree obtained, if any: BA Corporate Communications			
School Name: Homewood Flossmor H.S.		From - To (MM/YY – MM/YY): 08/98 - 05/02	
Address: 999 Kedzie Ave	City: Flossmoor	State: IL	Zip: 60422
Diploma/Degree obtained, if any: High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): 01/16 -Present	[redacted]	City: Coral Springs	State: FL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
DePuy Synthes Products Inc.			11/22 - Present	
Business Address	**City**		**State**	**Zip**
374 North Haverhill Road	West Palm Beach		FL	33415
Phone	**Title**		**Number of Employed Hours**	
815-757-7473	Senior Group Lead		approx. 6,000 hours	
Description of Duties				
Lead and develpoy a team of frontline leads & warehouse associates accross materials management, warehouse operation and finished good distribution.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Keafta Dokes, **certify that as the designated representative for**

DePuy Synthes Products Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. KRD I am at least 21 years of age;
3. KRD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. KRD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. KRD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. KRD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. KRD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Keafta Dokes

Print Name (First, Last)

Keafta Dokes

Original Signature (electronic, copies or stamps not accepted)

2/3/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Keafta Dokes
Print Name (First, Last)

Keafta Dokes
Original Signature (electronic, copies or stamps not accepted)

2/3/26
Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Palm Beach

I, Keafta Dokes ~~Christopher Y. Thomas~~, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Keafta Dokes
Original Signature

2/3/2026
Date

Subscribed and Sworn to before me this 2nd day of Feb 2026.

Notary Public Signature

Christopher Y. Thomas
Comm.: HH 388545
Expires: August 12, 2027
Notary Public - State of Florida

(Seal)

WWID	Last Name	Location	Current Work Country
152903355	Pendley	US244 FL Palm Beach	United States of America
188357	VILLARUZ	US244 FL Palm Beach	United States of America
1079959	Dirie	US244 FL Palm Beach	United States of America
421123	Hill	US244 FL Palm Beach	United States of America
420209	Cowrie	US244 FL Palm Beach	United States of America
1038097	Alcantara	US244 FL Palm Beach	United States of America
9726	ANANE	US244 FL Palm Beach	United States of America
170663	CHOHAN	US244 FL Palm Beach	United States of America
152308926	Lockhart	US244 FL Palm Beach	United States of America
369311	Miletic	US244 FL Palm Beach	United States of America
152951419	Burtner	US244 FL Palm Beach	United States of America
152906585	Etchison	US244 FL Palm Beach	United States of America
84001052	VARGAS	US244 FL Palm Beach	United States of America
1037038	DaSilva	US244 FL Palm Beach	United States of America
152983469	Keshavarz Panahi	US244 FL Palm Beach	United States of America
152914599	Brown	US244 FL Palm Beach	United States of America
411254	Gomez	US244 FL Palm Beach	United States of America
1079458	LANDIS	US244 FL Palm Beach	United States of America
152949295	Mukherjee	US244 FL Palm Beach	United States of America
155001863	Simpkins	US244 FL Palm Beach	United States of America
362526	TURK	US244 FL Palm Beach	United States of America
152963249	Regan	US244 FL Palm Beach	United States of America
411315	Valverde	US244 FL Palm Beach	United States of America
1068411	HALSEMA II	US244 FL Palm Beach	United States of America
411241	Meyer	US244 FL Palm Beach	United States of America
152214866	Paoli	US244 FL Palm Beach	United States of America
411236	Conover	US244 FL Palm Beach	United States of America
152234583	Sanford	US244 FL Palm Beach	United States of America
152231188	Sissel	US244 FL Palm Beach	United States of America
1035904	Grazin	US244 FL Palm Beach	United States of America
1070213	Bechard	US244 FL Palm Beach	United States of America
1072522	BLANCO	US244 FL Palm Beach	United States of America
411375	Peto	US244 FL Palm Beach	United States of America
152258199	Gomez	US244 FL Palm Beach	United States of America
152955589	Zulueta	US244 FL Palm Beach	United States of America
411312	Ramai	US244 FL Palm Beach	United States of America
152209382	Frost	US244 FL Palm Beach	United States of America
1035534	Parker	US244 FL Palm Beach	United States of America
1027678	Belger	US244 FL Palm Beach	United States of America
152307066	Lozano	US244 FL Palm Beach	United States of America
1052378	JEAN FELIX	US244 FL Palm Beach	United States of America
1052088	Isaza	US244 FL Palm Beach	United States of America
411377	Rimes	US244 FL Palm Beach	United States of America

368172	BARNETT	US244 FL Palm Beach	United States of America
152305375	Barnes	US244 FL Palm Beach	United States of America
152224971	Williamson	US244 FL Palm Beach	United States of America
152285857	Essary	US244 FL Palm Beach	United States of America
152905035	Baker	US244 FL Palm Beach	United States of America
152982870	Shannon	US244 FL Palm Beach	United States of America
417647	COLLINS	US244 FL Palm Beach	United States of America
1035055	Lill	US244 FL Palm Beach	United States of America
411263	Mullin	US244 FL Palm Beach	United States of America
155001824	Schiemann	US244 FL Palm Beach	United States of America
152910285	Warwick	US244 FL Palm Beach	United States of America
75592618	RESENDE DOS REIS	US244 FL Palm Beach	United States of America
152216308	Vasquez	US244 FL Palm Beach	United States of America
152981496	Dulgar	US244 FL Palm Beach	United States of America
1071597	Madrid-Rueda	US244 FL Palm Beach	United States of America
411242	Medina	US244 FL Palm Beach	United States of America
1049223	Massaro	US244 FL Palm Beach	United States of America
152304506	Miller	US244 FL Palm Beach	United States of America
152960206	Elejalde Aldana	US244 FL Palm Beach	United States of America
405151	Cloete	US244 FL Palm Beach	United States of America
411189	Palmer	US244 FL Palm Beach	United States of America
152968995	Harper	US244 FL Palm Beach	United States of America
411211	Sejour	US244 FL Palm Beach	United States of America
152943973	Cooper	US244 FL Palm Beach	United States of America
152219927	Keokhaw	US244 FL Palm Beach	United States of America
1074875	Schaffer	US244 FL Palm Beach	United States of America
411346	Brent	US244 FL Palm Beach	United States of America
1079230	YOUNG	US244 FL Palm Beach	United States of America
152241761	Allen	US244 FL Palm Beach	United States of America
152994173	Boutin	US244 FL Palm Beach	United States of America
72009941	Buck	US244 FL Palm Beach	United States of America
411327	Chamness	US244 FL Palm Beach	United States of America
1016799	Gonzales	US244 FL Palm Beach	United States of America
1060528	Thomas	US244 FL Palm Beach	United States of America
152215409	Pieper	US244 FL Palm Beach	United States of America
152948214	McLaughlin	US244 FL Palm Beach	United States of America
1074878	Marshall	US244 FL Palm Beach	United States of America
152976262	Soto	US244 FL Palm Beach	United States of America
1035432	McClain	US244 FL Palm Beach	United States of America
411465	Zegelien	US244 FL Palm Beach	United States of America
411295	Desrosiers	US244 FL Palm Beach	United States of America
124009365	GUTIERREZ	US244 FL Palm Beach	United States of America
1068576	Rogers	US244 FL Palm Beach	United States of America
1059741	FERRAZ	US244 FL Palm Beach	United States of America

411251	Jules-Irene	US244 FL Palm Beach	United States of America
152237320	Cata	US244 FL Palm Beach	United States of America
152234963	Jean	US244 FL Palm Beach	United States of America
411342	Bachota	US244 FL Palm Beach	United States of America
152942215	Dykes	US244 FL Palm Beach	United States of America
420599	Almendarez	US244 FL Palm Beach	United States of America
1076620	Edwards	US244 FL Palm Beach	United States of America
152905346	Haznedl	US244 FL Palm Beach	United States of America
376828	KLEER	US244 FL Palm Beach	United States of America
411167	Narducci	US244 FL Palm Beach	United States of America
152914582	Williams	US244 FL Palm Beach	United States of America
1043653	Van Tonder	US244 FL Palm Beach	United States of America
1035415	CORCORAN	US244 FL Palm Beach	United States of America
411218	Deluigi	US244 FL Palm Beach	United States of America
147000100	KRAUTER	US244 FL Palm Beach	United States of America
152255518	Cirino	US244 FL Palm Beach	United States of America
1054612	Saracino	US244 FL Palm Beach	United States of America
1073220	Camacho	US244 FL Palm Beach	United States of America
152183980	Fort	US244 FL Palm Beach	United States of America
1068421	Schwartz	US244 FL Palm Beach	United States of America
1070216	Deem	US244 FL Palm Beach	United States of America
1077923	Warren	US244 FL Palm Beach	United States of America
411160	Enck	US244 FL Palm Beach	United States of America
1052488	Mckenzie	US244 FL Palm Beach	United States of America
411205	Morales	US244 FL Palm Beach	United States of America
411307	Souza	US244 FL Palm Beach	United States of America
360609	WALLACE	US244 FL Palm Beach	United States of America
411869	Cubero	US244 FL Palm Beach	United States of America
152228012	Grant	US244 FL Palm Beach	United States of America
152992338	Umana	US244 FL Palm Beach	United States of America
411392	Parchment	US244 FL Palm Beach	United States of America
155001062	Burns	US244 FL Palm Beach	United States of America
362367	JACOBS	US244 FL Palm Beach	United States of America
152955558	Schlueter	US244 FL Palm Beach	United States of America
1055054	Crawford	US244 FL Palm Beach	United States of America
152281516	Alejo	US244 FL Palm Beach	United States of America
152891162	Singleton	US244 FL Palm Beach	United States of America
152992333	Jean Louis	US244 FL Palm Beach	United States of America
152199370	Branch	US244 FL Palm Beach	United States of America
152245820	Conniff	US244 FL Palm Beach	United States of America
411350	Schmitt	US244 FL Palm Beach	United States of America
371770	PANIZA	US244 FL Palm Beach	United States of America
152216642	Obando	US244 FL Palm Beach	United States of America
1059280	Andi	US244 FL Palm Beach	United States of America

158879	Gonzalez	US244 FL Palm Beach	United States of America
411271	Robles	US244 FL Palm Beach	United States of America
411302	Parchment	US244 FL Palm Beach	United States of America
152296685	Antoine	US244 FL Palm Beach	United States of America
1057083	ADONIS	US244 FL Palm Beach	United States of America
152226046	Spinelli	US244 FL Palm Beach	United States of America
152280705	Hunt	US244 FL Palm Beach	United States of America
1072387	BRAVO	US244 FL Palm Beach	United States of America
152910995	Chaux	US244 FL Palm Beach	United States of America
1064048	Mickam	US244 FL Palm Beach	United States of America
152896296	Thomas	US244 FL Palm Beach	United States of America
152219879	HEFTER	US244 FL Palm Beach	United States of America
152885045	Moreno Soto	US244 FL Palm Beach	United States of America
152234715	Nair	US244 FL Palm Beach	United States of America
411326	Buchanan	US244 FL Palm Beach	United States of America
152935153	Vincent	US244 FL Palm Beach	United States of America
1071406	Fernandez	US244 FL Palm Beach	United States of America
1070534	De Jesus-Carrero	US244 FL Palm Beach	United States of America
1072116	VICTORIA	US244 FL Palm Beach	United States of America
411248	King	US244 FL Palm Beach	United States of America
411212	Velasquez	US244 FL Palm Beach	United States of America
188607	DOMINGUEZ	US244 FL Palm Beach	United States of America
152968664	Steele	US244 FL Palm Beach	United States of America
411380	Keating	US244 FL Palm Beach	United States of America
152196430	Hussain	US244 FL Palm Beach	United States of America
152314781	Morales Montalvo	US244 FL Palm Beach	United States of America
152982804	Santana	US244 FL Palm Beach	United States of America
411289	Paulena	US244 FL Palm Beach	United States of America
152892823	Bastian	US244 FL Palm Beach	United States of America
1067409	Skinner	US244 FL Palm Beach	United States of America
411345	O'Brien	US244 FL Palm Beach	United States of America
152197651	Palacios	US244 FL Palm Beach	United States of America
152307767	Bailey	US244 FL Palm Beach	United States of America
1068112	Berndt	US244 FL Palm Beach	United States of America
152939228	Payne	US244 FL Palm Beach	United States of America
152301789	Hassel III	US244 FL Palm Beach	United States of America
1065626	Storms	US244 FL Palm Beach	United States of America
152210778	Christian	US244 FL Palm Beach	United States of America
152983465	Reynolds	US244 FL Palm Beach	United States of America
419856	Scafella	US244 FL Palm Beach	United States of America
411186	Mejia-Colossi	US244 FL Palm Beach	United States of America
417184	Stutzman	US244 FL Palm Beach	United States of America
411379	IMBERT-O'BRIEN	US244 FL Palm Beach	United States of America
152300233	Hatab	US244 FL Palm Beach	United States of America

152900538	Anderson	US244 FL Palm Beach	United States of America
411235	Beck	US244 FL Palm Beach	United States of America
154826	DUVALL	US244 FL Palm Beach	United States of America
152236961	Guisinger	US244 FL Palm Beach	United States of America
155001706	Payne	US244 FL Palm Beach	United States of America
411231	Battle	US244 FL Palm Beach	United States of America
411256	Brevil	US244 FL Palm Beach	United States of America
416565	Mandsager	US244 FL Palm Beach	United States of America
411462	Melbourne	US244 FL Palm Beach	United States of America
411232	Miller	US244 FL Palm Beach	United States of America
152302892	Bernstein	US244 FL Palm Beach	United States of America
377416	Haw	US244 FL Palm Beach	United States of America
152936244	BONILLA	US244 FL Palm Beach	United States of America
152233620	Maria	US244 FL Palm Beach	United States of America
1053262	Valenzuela	US244 FL Palm Beach	United States of America
411265	Murphy	US244 FL Palm Beach	United States of America
152304859	Jasmin	US244 FL Palm Beach	United States of America
152934645	Hazelet	US244 FL Palm Beach	United States of America
78015230	RAMIREZ	US244 FL Palm Beach	United States of America
152312291	Kim	US244 FL Palm Beach	United States of America
1073378	Everette III	US244 FL Palm Beach	United States of America
152228370	Hazard	US244 FL Palm Beach	United States of America
152301370	Anestin	US244 FL Palm Beach	United States of America
1030571	Buonanno	US244 FL Palm Beach	United States of America
1024927	Jacobsen	US244 FL Palm Beach	United States of America
152995161	Megino	US244 FL Palm Beach	United States of America
1010001	Brassel	US244 FL Palm Beach	United States of America
193922	EDWARDS	US244 FL Palm Beach	United States of America
152304799	Foerster	US244 FL Palm Beach	United States of America
152192199	Munoz-Perez	US244 FL Palm Beach	United States of America
152303500	Gamble	US244 FL Palm Beach	United States of America
152307905	Rodas Agustin	US244 FL Palm Beach	United States of America
152214298	Bengochea	US244 FL Palm Beach	United States of America
421257	Safont	US244 FL Palm Beach	United States of America
152299287	Tomas Alonzo	US244 FL Palm Beach	United States of America
152996870	Velasquez	US244 FL Palm Beach	United States of America
1031379	ROMERO	US244 FL Palm Beach	United States of America
1063163	EDWARDS	US244 FL Palm Beach	United States of America
152921892	Saras	US244 FL Palm Beach	United States of America
152934327	Perez	US244 FL Palm Beach	United States of America
152246952	Fernandez Santamaria	CH011 Synthes, Oberdorf	
152307642	Zapata	US244 FL Palm Beach	United States of America
411202	Colonna	US244 FL Palm Beach	United States of America
152960732	Shepherd	US244 FL Palm Beach	United States of America

152245581	Gaffikin	US244 FL Palm Beach	United States of America
152982090	Chowdhari	US244 FL Palm Beach	United States of America
201650	PARKER	US244 FL Palm Beach	United States of America
411243	Williams	US244 FL Palm Beach	United States of America
1053016	Proulx	US244 FL Palm Beach	United States of America
155001924	THOMAS	US244 FL Palm Beach	United States of America
1055238	Grazin	US244 FL Palm Beach	United States of America
1071855	Maharjan	US244 FL Palm Beach	United States of America
152910950	Tun	US244 FL Palm Beach	United States of America
152252446	Holzman	US244 FL Palm Beach	United States of America
1036606	Iyer	US244 FL Palm Beach	United States of America
1043309	Culp	US244 FL Palm Beach	United States of America
152184487	Dokes	US244 FL Palm Beach	United States of America
152250565	Scamperle	US244 FL Palm Beach	United States of America
410585	Gomez	US244 FL Palm Beach	United States of America
152999496	Nelson	US244 FL Palm Beach	United States of America
1041519	Taylor	US244 FL Palm Beach	United States of America
1044050	Rodriguez	US244 FL Palm Beach	United States of America
152207987	Degner	US244 FL Palm Beach	United States of America
411234	Mereus	US244 FL Palm Beach	United States of America
184881	DOYLE	US244 FL Palm Beach	United States of America
152307865	Gonzalez	US244 FL Palm Beach	United States of America
189838	JOHNSON	US244 FL Palm Beach	United States of America
152884203	Lawrence	US244 FL Palm Beach	United States of America
1030412	Naranjo	US244 FL Palm Beach	United States of America
152299180	Chimelis	US244 FL Palm Beach	United States of America
152905913	Wells	US244 FL Palm Beach	United States of America
152228020	Finkel	US244 FL Palm Beach	United States of America
411466	Bhawsar	US244 FL Palm Beach	United States of America
152310854	Cartwright	US244 FL Palm Beach	United States of America
411374	Feikert	US244 FL Palm Beach	United States of America
367989	DOMINGUEZ	US244 FL Palm Beach	United States of America
411213	Williams	US244 FL Palm Beach	United States of America
416089	Williams	US244 FL Palm Beach	United States of America
1044249	Nelson	US244 FL Palm Beach	United States of America
411252	Oconnor	US244 FL Palm Beach	United States of America
411183	Smith	US244 FL Palm Beach	United States of America
152936012	Jacobson	US244 FL Palm Beach	United States of America
411276	Jean-Baptiste	US244 FL Palm Beach	United States of America
152199360	Klauka	US244 FL Palm Beach	United States of America
1022053	Schaefer	US244 FL Palm Beach	United States of America
411199	Boroos	US244 FL Palm Beach	United States of America
1004087	Gauthier	US244 FL Palm Beach	United States of America
419840	Triolo	US244 FL Palm Beach	United States of America

1030452	Warwick	US244 FL Palm Beach	United States of America
152962593	Wright	US244 FL Palm Beach	United States of America
152199126	Ramirez	US244 FL Palm Beach	United States of America
1062165	Troche	US244 FL Palm Beach	United States of America
152952725	O'Brien	US244 FL Palm Beach	United States of America
411301	Morales	US244 FL Palm Beach	United States of America
152912145	De Nadai	US244 FL Palm Beach	United States of America
152226800	Henriques	US244 FL Palm Beach	United States of America
152300166	Dubelier	US244 FL Palm Beach	United States of America
66100	EDGAR	US244 FL Palm Beach	United States of America
152310485	Wilson	US244 FL Palm Beach	United States of America
152935439	Tamayo	US244 FL Palm Beach	United States of America
97000478	RAMIREZ	US244 FL Palm Beach	United States of America
1068217	Valencia Duran	US244 FL Palm Beach	United States of America
152983874	Garcia	US244 FL Palm Beach	United States of America
152929205	Martinez Jerez	US244 FL Palm Beach	United States of America
152306739	Rodas	US244 FL Palm Beach	United States of America
411171	TASSI	US244 FL Palm Beach	United States of America
152957884	Avila	US244 FL Palm Beach	United States of America
1048447	Bernadin	US244 FL Palm Beach	United States of America
152245124	Pimentel Diaz	US244 FL Palm Beach	United States of America
411280	Alexandre	US244 FL Palm Beach	United States of America
1071330	Perez Garcia	US244 FL Palm Beach	United States of America
419765	CHINEZ	US244 FL Palm Beach	United States of America
420941	Costanzo	US244 FL Palm Beach	United States of America
152234503	DelVecchio	US244 FL Palm Beach	United States of America
152965782	Despathy	US244 FL Palm Beach	United States of America
411172	Zimmerman	US244 FL Palm Beach	United States of America
1048220	Geffrard	US244 FL Palm Beach	United States of America
417807	Slane	US244 FL Palm Beach	United States of America
1074869	Ershery-Stokely	US244 FL Palm Beach	United States of America
152985971	Young	US244 FL Palm Beach	United States of America
152999036	Ponton	US244 FL Palm Beach	United States of America
1000470	Riley Johnson	US244 FL Palm Beach	United States of America
367290	CARDINALE	US244 FL Palm Beach	United States of America
1037707	Dookhran	US244 FL Palm Beach	United States of America
335134	HARRIGAN	US244 FL Palm Beach	United States of America
411164	Menard	US244 FL Palm Beach	United States of America
1060843	Thompson	US244 FL Palm Beach	United States of America
152902987	Weaver	US244 FL Palm Beach	United States of America
1072393	GOODEN	US244 FL Palm Beach	United States of America
152313935	Greenberg	US244 FL Palm Beach	United States of America
370572	PLASTOW	US244 FL Palm Beach	United States of America
411230	Kelly	US244 FL Palm Beach	United States of America

1064102	Bartoe	US244 FL Palm Beach	United States of America
169250	WAAS	US244 FL Palm Beach	United States of America
152307764	Asawla	US244 FL Palm Beach	United States of America
152304865	Sanchez	US244 FL Palm Beach	United States of America
1070093	SANTOS ROZO	US244 FL Palm Beach	United States of America
1041236	Rehmatullah	US244 FL Palm Beach	United States of America
411385	Garcia	US244 FL Palm Beach	United States of America
152989388	Raber	US244 FL Palm Beach	United States of America
1014766	MEDEIROS	US244 FL Palm Beach	United States of America
1035253	Brierre	US244 FL Palm Beach	United States of America
152944718	Du	US244 FL Palm Beach	United States of America
1061276	RATCLIFF	US244 FL Palm Beach	United States of America
1024643	Holland	US244 FL Palm Beach	United States of America
1025042	Roman	US244 FL Palm Beach	United States of America
411317	Jean-Baptiste	US244 FL Palm Beach	United States of America
1077350	SANTIAGO	US244 FL Palm Beach	United States of America
1004012	Hellrung	US244 FL Palm Beach	United States of America
152935781	Saporito	US244 FL Palm Beach	United States of America
152981901	Fenghea	US244 FL Palm Beach	United States of America
411296	Fraguela	US244 FL Palm Beach	United States of America
1043582	CAGONOT	US244 FL Palm Beach	United States of America
1041553	Theuri	US244 FL Palm Beach	United States of America
152304038	Frances	US244 FL Palm Beach	United States of America
411190	Richards	US244 FL Palm Beach	United States of America
1041976	Jara-Hazelet	US244 FL Palm Beach	United States of America
152309251	Zamora Diaz	US244 FL Palm Beach	United States of America
1038295	Gonzalez	US244 FL Palm Beach	United States of America
363577	JURCZYNSKI	US244 FL Palm Beach	United States of America
411180	Maier	US244 FL Palm Beach	United States of America
1044420	SKINNER	US244 FL Palm Beach	United States of America
152262790	Manda	US244 FL Palm Beach	United States of America
152941593	Grogan	US244 FL Palm Beach	United States of America
152303021	PATEL	US244 FL Palm Beach	United States of America
152969583	Warren	US244 FL Palm Beach	United States of America
1070398	Xu	US244 FL Palm Beach	United States of America
1035344	Ceres	US244 FL Palm Beach	United States of America
1069317	VALENTIN VAZQUEZ	US244 FL Palm Beach	United States of America
1061575	Maharjan	US244 FL Palm Beach	United States of America
420267	Megino	US244 FL Palm Beach	United States of America
152949967	Martinez	US244 FL Palm Beach	United States of America
1051773	Richards	US244 FL Palm Beach	United States of America
1075276	Goslin	US244 FL Palm Beach	United States of America
152309499	Henderson	US244 FL Palm Beach	United States of America
152910564	Head	US244 FL Palm Beach	United States of America

411388	Clarke	US244 FL Palm Beach	United States of America
152247634	Castro	US244 FL Palm Beach	United States of America
411176	Gill	US244 FL Palm Beach	United States of America
411163	Lopez	US244 FL Palm Beach	United States of America
27418	CONTINO	US244 FL Palm Beach	United States of America
178340	DOOKHRAN	US244 FL Palm Beach	United States of America
152302912	Heins	US244 FL Palm Beach	United States of America
152964695	Walther	US244 FL Palm Beach	United States of America
1030457	Moss	US244 FL Palm Beach	United States of America
411238	Gonzalez	US244 FL Palm Beach	United States of America
375843	DIAZ	US244 FL Palm Beach	United States of America
152273581	Jones	US244 FL Palm Beach	United States of America
411154	Bent	US244 FL Palm Beach	United States of America
152200016	Bravo	US244 FL Palm Beach	United States of America
152964905	Rodrigue	US244 FL Palm Beach	United States of America
152220235	Yera	US244 FL Palm Beach	United States of America
152998543	Vivas	US244 FL Palm Beach	United States of America
1061209	KLINE	US244 FL Palm Beach	United States of America
152258082	Donahoe	US244 FL Palm Beach	United States of America
411387	Phillips	US244 FL Palm Beach	United States of America
152278559	Uber	US244 FL Palm Beach	United States of America
1072992	GIRI	US244 FL Palm Beach	United States of America
152992858	Ross	US244 FL Palm Beach	United States of America
152301667	Simpkins	US244 FL Palm Beach	United States of America
1072358	OBEROI	US244 FL Palm Beach	United States of America
201574	BRIZO	US244 FL Palm Beach	United States of America
1001763	Kleer	US244 FL Palm Beach	United States of America
421258	Joseph	US244 FL Palm Beach	United States of America
152209861	Vakulabharanam	US244 FL Palm Beach	United States of America
152941102	Kalidindi	US244 FL Palm Beach	United States of America
410681	Jacobs	US244 FL Palm Beach	United States of America
417163	Lawrence	US244 FL Palm Beach	United States of America
152984358	Caicedo	US244 FL Palm Beach	United States of America
152309064	FAUSTIN	US244 FL Palm Beach	United States of America
1036915	Cloete	US244 FL Palm Beach	United States of America
1008597	Crossen	US244 FL Palm Beach	United States of America
152992843	Johnson	US244 FL Palm Beach	United States of America
152886709	Josse	US244 FL Palm Beach	United States of America
363844	YODER	US244 FL Palm Beach	United States of America
1064609	Lobban	US244 FL Palm Beach	United States of America
152955906	Robinson	US244 FL Palm Beach	United States of America
152979179	Dahal Ghimire	US244 FL Palm Beach	United States of America
1031807	Patteuw	US244 FL Palm Beach	United States of America
411285	Julien	US244 FL Palm Beach	United States of America

152299833	BAILEY	US244 FL Palm Beach	United States of America
152277598	Paradi	US244 FL Palm Beach	United States of America
174634	ROGASKI	US244 FL Palm Beach	United States of America
1042742	Bravo	US244 FL Palm Beach	United States of America
152991427	Starkey	US244 FL Palm Beach	United States of America
1032526	Holden	US244 FL Palm Beach	United States of America
1073993	RITTER	US244 FL Palm Beach	United States of America
152288913	Ozga	US244 FL Palm Beach	United States of America
152239181	Motes	US244 FL Palm Beach	United States of America
176159	Palmer	US244 FL Palm Beach	United States of America
152303382	Pollock	US244 FL Palm Beach	United States of America
1069949	Lynch	US244 FL Palm Beach	United States of America
152995817	Graham	US244 FL Palm Beach	United States of America
152304013	Williams	US244 FL Palm Beach	United States of America
411334	Mc Caulley	US244 FL Palm Beach	United States of America
152222385	Burkin	US244 FL Palm Beach	United States of America
377406	SMALL	US244 FL Palm Beach	United States of America
371443	McAfee	US244 FL Palm Beach	United States of America
1070239	Philipson	US244 FL Palm Beach	United States of America
1013899	Sippel	US244 FL Palm Beach	United States of America
420098	Steiner	US244 FL Palm Beach	United States of America
371990	WATKINSON	US244 FL Palm Beach	United States of America
1040570	Nguyen	US244 FL Palm Beach	United States of America
1047666	Rodts	US244 FL Palm Beach	United States of America
152303787	Savage	US244 FL Palm Beach	United States of America
373753	Tarantelli	US244 FL Palm Beach	United States of America
154590	MESERVE	US244 FL Palm Beach	United States of America
152254571	Weissman	US244 FL Palm Beach	United States of America
152937313	Hannah	US244 FL Palm Beach	United States of America
1068381	Tyler	US244 FL Palm Beach	United States of America
152952903	Drew	US244 FL Palm Beach	United States of America
152931010	Leichty	US244 FL Palm Beach	United States of America
411288	Nguyen	US244 FL Palm Beach	United States of America
1043408	Yepez	US244 FL Palm Beach	United States of America
411228	Doubleday	US244 FL Palm Beach	United States of America
339005	BARRE	US244 FL Palm Beach	United States of America
152308714	Geschleider	US244 FL Palm Beach	United States of America
152275835	Imbert	US244 FL Palm Beach	United States of America
411283	Charles	US244 FL Palm Beach	United States of America

Worker Type	Time Type
Employee	Full time
Employee	Full time
Employee	Full time

Employee	Full time
Employee	Full time
Employee	Full time

Employee	Full time
Employee	Full time
Employee	Full time

Employee	Full time
Employee	Full time
Employee	Full time

Employee	Full time
Employee	Full time
Employee	Full time

Employee	Full time
Employee	Full time
Employee	Full time

Employee	Full time
Employee	Full time
Employee	Full time

Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Part time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full time
Employee	Full

Employee	Full time
Employee	Full time
Employee	Full time

Employee	Full time
Employee	Full time
Employee	Full time

4U

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Fisher & Paykel Healthcare, Inc.

Physical Address: 511 Harley Knox Blvd.

City: Perris State: CA Zip: 92571

Mailing Address (if different from physical address): 17400 Laguna Canyon Road #300

City: Irvine State: CA Zip: 92618

Telephone: 949-453-4000 Website: www.fphcare.com

Name of Designated Representative (DR): Christopher Leyva

Licensing Company Email: Compliance.USA@fphcare.com DR Email: Chris.Leyva@fphcare.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: DMES		■ Others: Distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*: N/A

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8-14-2026
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Fisher & Paykel Healthcare - New Zealand
Address: 15 Maurice Paykel Place, East Tamaki City: Auckland State: NZ Zip: 2013

Name: MAXTEC
Address: 2305 South 1070 West City: Salt Lake City State: UT Zip: 84119

Name: Precision Medical
Address: 300 Held Drive City: Northampton State: PA Zip: 18067

Name: Ohio Medical
Address: 1111 Lakeside Drive City: Gurnee State: IL Zip: 60031

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California
Parent Company (if any): Fisher & Paykel Holdings, Inc.
Corporation/Organization Name: Fisher & Paykel Healthcare, Inc.
Mailing Address: 17400 Laguna Canyon Road #300
City: Irvine State: CA Zip: 92618
Telephone: 949-453-4000 Email: Compliance.USA@fphcare.com
Contact Person Name: Compliance Department

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

	Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
	• **List of all Officers and Directors.**	✓	✓		
N/A	• **List the top four corporation shareholders and their percent ownership.**	✓			
	• **List of all corporation shareholders and their percent ownership.**		✓		
N/A	• **List of all partners and their percent ownership.**			✓	
	• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
	• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
N/A	• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
N/A	• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
N/A	• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
	• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
	• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
	• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
	• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
	ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
N/A	• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
N/A	• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Fisher & Paykel Healthcare, Inc.

Facility Name

Rebecca Lee

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9-14-2026

Date

Board Use Only	Date Received: 9/17/26	Amount: $1000 ch# 12292

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
Fisher & Paykel Healthcare, INC
511 Harley Knox Blvd
Perris, CA 92571
Registration Number: 3031126394
FEI Number*: 3031126394
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types. Please Review Listings For Further Information.
Date Of Registration Status: 2026

Owner/Operator:
FISHER & PAYKEL HEALTHCARE NZ LTD[6]
15 MAURICE PAYKEL PLACE
EAST TAMAKI, AUCKLAND 2013 NZ
Owner/Operator Number: 8040217[7]

Official Correspondent:
Diego Vargas Banuelos
17400 Laguna Canyon Road, Suite 300
Irvine, CA 92618
Phone: 001-949-4341005

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

---

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=8040217&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=8040217&OwnerOperator

Verified M.H 5/19/26

Page Last Updated: 08/10/2026

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsc | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of **Health & Human Services**

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=8040217&OwnerOperator

INFORMATION AS OF August 10, 2026

Fisher & Paykel Healthcare Inc.

Position		Name	Address
Director	Director	Andrew Niccol	15 Maurice Paykel Place, East Tamaki, Auckland NZ 2013
Director	Director	Justin Callahan	17400 Laguna Canyon Road #300, Irvine CA 92618
Director	Director	Steven Wilson	17400 Laguna Canyon Road #300, Irvine CA 92618
Officer	President	Steven Wilson	17400 Laguna Canyon Road #300, Irvine CA 92618
Officer	Secretary/Treasurer	Bryan Goudzwaard	17400 Laguna Canyon Road #300, Irvine CA 92618

CONFIDENTIAL

List of Owners - Fisher & Paykel Healthcare Inc.

Fisher & Paykel Holdings Inc. (100% ownership)
17400 Laguna Canyon Road #300
Irvine, CA 92618
Office: 949-453-4000
FEIN: 33-0721612

Fisher & Paykel Healthcare, Inc
17400 Laguna Canyon Road #300
Irvine, CA 92618
Office: 949-453-4000
FEIN: 33-0675741

Steven Wilson- **President**
17400 Laguna Canyon Road #300
Irvine, CA 92618
Ph#: 949-453-4000
E-mail: Compliance.USA@fphcare.com

Bryan Goudzwaard- **Secretary**
17400 Laguna Canyon Road #300
Irvine, CA 92618
Ph#: 949-453-4000
E-mail: Compliance.USA@fphcare.com

Fisher & Paykel
HEALTHCARE

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	FISHER & PAYKEL HEALTHCARE, INC.
Entity No.:	1923631
Registration Date:	08/09/1995
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of May 19, 2026.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 459935330

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

CA dca SEARCH

BOARD OF PHARMACY

ISSUANCE DATE
SEPTEMBER 5, 2024

EXPIRATION DATE
SEPTEMBER 1, 2027

CURRENT DATE / TIME
AUGUST 10, 2026
1:16:42 PM

LICENSING DETAILS FOR: WLS 8464

NAME: FISHER & PAYKEL HEALTHCARE INC

LICENSE TYPE: WHOLESALER

LICENSE STATUS: CLEAR

ADDRESS
511 HARLEY KNOX BLVD
PERRIS CA 92571
RIVERSIDE COUNTY

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 03/27/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Marsh Risk & Insurance Services
17901 Von Karman Avenue, Suite 1100
(949) 399-5800, License #0437153
Irvine, CA 92614

CN103180339-STND-GAWU-26-27

INSURED
Fisher and Paykel Healthcare Inc. USA
17400 Laguna Canyon Road #300
Irvine, CA 92618

CONTACT NAME:
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : ACE American Insurance Company	22667
INSURER B : Federal Insurance Company	20281
INSURER C : Chubb Indemnity Insurance Co	12777
INSURER D :	
INSURER E :	
INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** LOS-002761198-03 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			G46673682	04/01/2026	04/01/2027	EACH OCCURRENCE	$	2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	2,000,000
							MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	2,000,000
	OTHER:						Ded Limits	$	5,000
B	AUTOMOBILE LIABILITY			73602449	04/01/2026	04/01/2027	COMBINED SINGLE LIMIT (Ea accident)	$	1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY X SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	X HIRED AUTOS ONLY NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$	
	DED RETENTION $							$	
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			71756721	04/01/2026	04/01/2027	X PER STATUTE OTH-ER		
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N / A (Mandatory in NH)						E.L. EACH ACCIDENT	$	1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence Of Insurance

CERTIFICATE HOLDER
Fisher & Paykel Healthcare, Inc.
511 Harley Knox Blvd
Perris, CA 92571

CANCELLATION
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Marsh Risk & Insurance Services

© 1988-2016 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: CN103180339

LOC #: Irvine

ADDITIONAL REMARKS SCHEDULE

AGENCY		NAMED INSURED
Marsh Risk & Insurance Services		Fisher and Paykel Healthcare Inc. USA 17400 Laguna Canyon Road #300 Irvine, CA 92618
POLICY NUMBER		
CARRIER	NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

The (General Liability, Chub Insurance New Zealand, AGEL401312) placement was made by Marsh New Zealand. Marsh USA LLC has only acted in the role of a consultant to the client with respect to this placement, which is indicated here for your convenience.

© 2008 ACORD CORPORATION. All rights reserved.

The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 20BSBJF2439

Application/License No. _____

Fisher & Paykel Healthcare, Inc., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
511 Harley Knox Boulevard, Perris, CA 92571, as
(Address of Applicant/Principal)
PRINCIPAL, and Hartford Fire Insurance Company, a
(Surety Company)
corporation organized under the laws of the state of Connecticut
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
One Hartford Plaza Hartford, CT 06155 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on May 14, 2024.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

20BSBJF2439

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 14th day of May, 2024.

APPLICANT/PRINCIPAL

Fisher & Paykel Healthcare, Inc.

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Shelby Russell, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Sarah Major

Witness Bonnie Rice

Countersigned by:

N/A

Nevada Resident Agent

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: MARSH USA LLC
Agency Code: 20-246454

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint Shelby Russell

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:

Bond No. 20BSBJF2039
Naming Fisher & Paykel Healthcare, Inc. as Principal,
and Nevada State Board Of Pharmacy as Obligee,

in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of May 19, 2024.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Fisher & Paykel Healthcare, Inc. MDEG License # (if applicable): _____

Physical Address: 511 Harley Knox Blvd

City: Perris State: CA Zip: 92571

Mailing Address (if different from physical address): 17400 Laguna Canyon Road #300

City: Irvine State: CA Zip: 92618

Telephone: 949-453-4000 Website: www.fphcare.com

Licensing Company Email: Compliance.USA@fphcare.com

Section 2: Personal Information

First: Christopher Middle: _____ Last: Leyva

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITI: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 17400 Laguna Canyon Road #300

City: Irvine State: CA Zip: 92618

Telephone: 949-453-4000 Email: Compliance.USA@fphcare.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Phoenix		09/18-09/20	
Address	City	State	Zip
4035 S. Riverpoint Pkwy	Phoenix	AZ	85040
Diploma/Degree obtained, if any			
Bachelor Degree in Business Management			

School Name		From - To (MM/YY – MM/YY)	
Ontario High School			
Address	City	State	Zip
901 W. Francis St	Ontario	CA	91762
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/19-current	[redacted]	Riverside	CA	[redacted]
01/14-01/19		Ontario	CA	

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Fisher & Paykel Healthcare Inc.			03/29/2021-current
Business Address	**City**	**State**	**Zip**
511 Harley Knox Blvd	Perris	CA	92571
Phone	**Title**	**Number of Employed Hours**	
949-453-4000	Assistant DC Manager, Distribution Center Manager	1,500+	
Description of Duties			
Lead, direct, manage and develop employees; provide input to plan for future growth and facilitate the delivery of finished goods to customers, liaise with customer service, and transport providers. Maintain and monitor environment, etc.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:** N/A

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11-AUG-2026
Date

I, Christopher Leyva, **certify that as the MDEG Administrator for**

Fisher & Paykel Healthcare, Inc.,

that I (initial that you have read and meet the following requirements):

1. CL Have a high school diploma or its equivalent;
2. CL Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CL Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CL Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Leyva
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-AUG-2026
Date

Board Use Only	Date Received: 8/11/26

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Fisher & Paykel Healthcare, Inc.

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 511 Harley Knox Blvd

City: Perris State: CA Zip: 92571

Mailing Address (if different from physical address): 17400 Laguna Canyon Road #300

City: Irvine State: CA Zip: 92618

Telephone: 949-453-4000 Website: www.fphcare.com

Licensing Company Email: Compliance.USA@fphcare.com

Section 2: Personal Information

First: Christopher Middle: Last: Leyva

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or I[redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 17400 Laguna Canyon Road #300

City: Irvine State: CA Zip: 92618

Telephone: 949-453-4000 Email: Compliance.USA@fphcare.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Phoenix		09/18-09/20	
Address	**City**	**State**	**Zip**
4035 S. Riverpoint Pkwy	Phoenix	AZ	85040
Diploma/Degree obtained, if any			
Bachelor Degree in Business Management			
School Name		From - To (MM/YY – MM/YY)	
Ontario High School			
Address	**City**	**State**	**Zip**
901 W. Francis St	Ontario	CA	91762
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/19-current	[redacted]	Riverside	CA	[redacted]
01/14-01/19		Ontario	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Fisher & Paykel Healthcare Inc.			03/29/2021-current	
Business Address	**City**		**State**	**Zip**
511 Harley Knox Blvd	Perris		CA	92571
Phone	**Title**		**Number of Employed Hours**	
949-453-4000	Assistant DC Manager, Distribution Center Manager		6,000 +	
Description of Duties				
Lead, direct, manage and develop employees; provide input to plan for future growth and facilitate the delivery of finished goods to customers, liaise with customer service, and transport providers. Maintain and monitor environment, etc.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

N/A

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11-AUG-2026
Date

I, Christopher Leyva, **certify that as the designated representative for**

Fisher & Paykel Healthcare, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. X, CL I am at least 21 years of age;
3. X, CL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X, CL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X, CL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X, CL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X, CL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christopher Leyva

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11-AUG-2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Leyva

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/11/2026

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Riverside

I, Chris Leyva, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11-AUG-2026

Date

Subscribed ~~and Sworn~~ to before me this 11 day of August, 2026

Notary Public Signature

OLGA R. CANNADY
COMM. #2454840
Notary Public · California
Riverside County
My Comm. Expires Aug. 20, 2027

NRO1 NRO1

(Seal)

Fisher & Paykel Healthcare, Inc
511 Harley Knox Blvd
Perris, Ca 92571

Employee List:

Bustillos, Joseph

Figueroa, Guillermo Ramirez

Guzman, Stephanie M

Hamilton, Victor A

Hernandez-Saldana, Anthony

Jimenez, Ruben

Leyva, Christopher J

Lopez, William

Martinez, Valentin

Munoz, Jason

Partida, Lorenzo

Ramos, Armando

Romero, Luis

Ruvalcaba, Jose R.

Samy, Mun

Serna, Alfred

Sevilla, Juan Gabriel

Williams, Chelsie M.

Williams, Jamilah

Zendejas, Yasmin

CONFIDENTIAL

4V

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10) ■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10)

Section 1: General Information

Facility Name: Kanchan Healthcare Inc

Physical Address: 1 Gatehall Dr., Ste 202

City: Parsippany State: NJ Zip: 07054

Mailing Address (if different from physical address): 1 Gatehall Dr., Ste 202

City: Parsippany State: NJ Zip: 07054

Telephone: 973-969-2797 Website: _____

Name of Designated Representative (DR): Dev Kumar Singh

Licensing Company Email: kanchan@AltaLawGroup.com DR Email: kanchan@AltaLawGroup.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies ☐ Practitioners ☐ Hospitals ■ Wholesalers ☐ Veterinarians ☐ Others:	■ Dangerous Drugs ■ Controlled Substances ☐ [a]Medical Products (medical devices, equipment, supplies, gases) ☐ Others:	■ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ☐ Others:

Section 2: ONLY COMPLETE THIS SECTION IF THE COMPANY IS WHOLESALING [a]Medical Products (medical devices, equipment, supplies and gases). Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 3 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 4: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Medley Pharmaceuticals Limited
Address: Plot No. 18 and 19, Zari Causeway Road, City: Daman State: India Zip: 396210

Name: AptaPharma Inc.
Address: 1533 Union Avenue City: Pennsauken State: NJ Zip: 08110

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Section 5: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any):
Corporation/Organization Name: Kanchan Healthcare Inc
Mailing Address: 1 Gatehall Dr., Ste 202
City: Parsippany State: NJ Zip: 07054
Telephone: 973-969-2797 Email: kanchan@AltaLawGroup.com
Contact Person Name: Tanya Dobash

Section 7: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 8: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Kanchan Healthcare Inc

Facility Name

Dev Kumar Singh

Print Name of Authorized Person Submitting Application



Original signature of Authorized Person (copies or stamps not accepted)

June 2, 2026

Date

Board Use Only	Date Received: 7/27/26	Amount: $1000.00

Section 9: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration FDA labeler code 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 10: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale [a]Medical Products (medical devices, equipment, supplies, gases). (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Products (medical devices, equipment, supplies, gases), supply a copy of proof of insurance (NAC 639.6957).** The Medical Products wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 9)				
• **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20NRS%20639.500%20-%20Effective%2001.07.2026%20-%20Wholesaler%20-%20Post%20on%201.26.26.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

KANCHAN HEALTHCARE INC

FDA Labeler Code

Kanchan Healthcare Inc holds FDA labeler code 85742.

From: edrls@fda.hhs.gov <edrls@fda.hhs.gov>
Sent: Wednesday, May 28, 2025 11:01 AM
To: Dev Kumar Singh <dev@kanchanglobal.com>
Subject: Labeler Code Request Approved

eDRLS - Electronic Drug Registration & Listing System

Current Date: 28-MAY-2025
Labeler DUNS: 119315087
Labeler Name: Kanchan Healthcare Inc
Labeler Code Assigned: 85742

✓ verified M.H 8/5/26

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

KANCHAN HEALTHCARE INC

Company Information

Date of Incorporation: May 28, 2024
State of Incorporation: Delaware
Entity Type: Corporation
Tax ID: 99-3318462

Address: 1 Gatehall Dr., Ste 202, Parsippany, NJ 07054

Shareholders:
Kanchan Healthcare Int LLP - 100%

Corporate Officer:
Dev Kumar Singh
Chief Executive Officer
1 Gatehall Dr., Ste 202, Parsippany, NJ 07054

Designated Representative:
Dev Kumar Singh
Chief Executive Officer
1 Gatehall Dr., Ste 202, Parsippany, NJ 07054

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "KANCHAN HEALTHCARE INC" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWELFTH DAY OF JUNE, A.D. 2026.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

3780492 8300

SR# 20263386132

Authentication: 204218914

Date: 06-12-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

KANCHAN HEALTHCARE INC
0451283459

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named Delaware Foreign For-Profit Corporation was registered by this office on May 08, 2025.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

DEV KUMAR SINGH
1 GATEHALL DRIVE
SUITE 202
PARSIPPANY, NJ 07054

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 24th day of July, 2026

Aaron Binder

Aaron Binder
State Treasurer

Certificate Number : 6179483648

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

KANCHAN HEALTHCARE INC

Home State License Certificate

Kanchan Healthcare Inc holds New Jersey license # 5006751, which expires January 31, 2027.



NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE
0025601
P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written noticeprior to the change of the address of such new location and the name and address of the individual to be in charge thereof.A fee of $20.00 shall accompanying such notification."

Registered as: ☑ Manufacturer ☑ Distributor which conducts business at the following locations:

Reg. No.: 5006751

KANCHAN HEALTHCARE INC
1 GATEHALL DR STE 202
PARSIPPANY, NJ 07054

ISSUED PURSUANT TO:
N.J.S.A. 24:6B
EXPIRES: January 31, 2027

Establishment Copy

3PL DEA Certificate

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	04-30-2027	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-04-2026

RXCROSSROADS 3PL LLC
4200 BINION WAY STE 200
MASON, OH 450369469

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	04-30-2027	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-04-2026

RXCROSSROADS 3PL LLC
4200 BINION WAY STE 200
MASON, OH 450369469

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 3010132

Application/License No. _____

Kanchan Healthcare Inc (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1 Gatehall Dr., Ste 202, Parsippany, NJ 07054 (Address of Applicant/Principal), as PRINCIPAL, and Harco National Insurance Company (Surety Company), a corporation organized under the laws of the state of Illinois (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 4200 Six Forks Rd, Suite 1400, Raleigh, NC 27609 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 06/22/2026 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 22nd day of June, 2026.

APPLICANT/PRINCIPAL

Kanchan Healthcare Inc

Authorized Representative

Dev Kumar Singh, CEO

SURETY COMPANY

Harco National Insurance Company

Surety Company's Representative

Sharif Ismail, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent Shani Ismail

POWER OF ATTORNEY

Bond # 3010132

HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 4200 Six Forks Rd, Suite 1400, Raleigh, NC 27609

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

RALF RIGO, SHARIF ISMAIL

Syracuse, NY

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2025

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1904 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1904 ILLINOIS

Michael F. Zurcher
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2025, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

CATHY CRUZ NOTARY PUBLIC STATE OF NEW JERSEY

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Cathy Cruz a Notary Public of New Jersey
My Commission Expires April 16, 2029

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, June 22, 2026

A00816

Irene Martins, Assistant Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Kanchan Healthcare Inc

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 1 Gatehall Dr., Ste 202

City Parsippany State NJ Zip 07054

Mailing Address (if different from physical address) 1 Gatehall Dr., Ste 202

City Parsippany State NJ Zip 07054

Telephone 973-969-2797 Website _____

Licensing Company Email kanchan@altalawgroup.com

Section 2: Personal Information

First Dev Middle Kumar Last Singh

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 1 Gatehall Dr., Ste 202

City Parsippany State NJ Zip 07054

Telephone 973-969-2797 Email dev@kanchanglobal.com

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Lucknow		1993-1995	
Address	**City**	**State**	**Zip**
Babuganj, Hasanganj	Lucknow	India	226007
Diploma/Degree obtained, if any			
Masters of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Colvin Taluqdars College		1975-1986	
Address	**City**	**State**	**Zip**
University Rd	Lucknow	India	226007
Diploma/Degree obtained, if any			
Intermediate, Science			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/16 to present	[redacted]	Parsippany	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Kanchan Healthcare Inc			01/25 to present	
Business Address		**City**	**State**	**Zip**
1 Gatehall Dr., Ste 202		Parsippany	NJ	07054
Phone	**Title**		**Number of Employed Hours**	
973-969-2797	CEO		3,650	
Description of Duties				
Oversee all company functions for pharmaceutical manufacturer/wholesaler, including operations, prescription drug sales and distribution matters, recordkeeping related to same, compliance with legal and regulatory requirements.				

Business Name			From - To (MM/YY – MM/YY)	
Leading Pharma, LLC			11/17 to 12/25	
Business Address		**City**	**State**	**Zip**
3 Oak Rd		Fairfield	NJ	07004
Phone	**Title**		**Number of Employed Hours**	
973-276-9600	Chief Operating Officer		19,300	
Description of Duties				
Oversee operations including prescription drug warehousing and distribution matters, record keeping related to same, and compliance with legal and regulatory requirements.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

08/07/2026
Date

I, Dev Kumar Singh, **certify that as the designated representative for**

Kanchan Healthcare Inc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AS I am at least 21 years of age;
3. AS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Dev Kumar Singh

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/07/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dev Kumar Singh
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/07/2026
Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of _____

I, Dev Kumar Singh, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

08/07/2026
Date

Subscribed and Sworn to before me this 7th day of Aug. 2026

Notary Public Signature

GUNVANTBHAI V PATEL
NOTARY PUBLIC NEW JERSEY
MY COMMISSION EXP. FEB 02 2030
NO.50009407

(Seal)

KANCHAN HEALTHCARE INC

Employee List

Dev Kumar Singh, CEO
Sonal Patel, Administrative Assistant

4W

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10)

Section 1: General Information

Facility Name: Luria Therapeutics LLC

Physical Address: 10411 Corporate Drive, Suite 108

City: Pleasant Prairie State: WI Zip: 53158

Mailing Address (if different from physical address): 10411 Corporate Drive, Suite 108

City: Pleasant Prairie State: Wisconsin Zip: 53158

Telephone: (877) 587-4299 Website: _____

Name of Designated Representative (DR): James DeFranco

Licensing Company Email: statelicensing@luriapharma.com DR Email: james.defranco@luriapharma.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☒ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☐ *Medical Products (medical devices, equipment, supplies, gases)	☐ Reverse Distributor
☒ Wholesalers		☐ Warehouse
☐ Veterinarians	☐ Others:	☐ Retail pharmacy wholesale distributor
☒ Others: Military, Spec. Distributors		☐ Others:

Section 2: ONLY COMPLETE THIS SECTION IF THE COMPANY IS WHOLESALING [a]Medical Products (medical devices, equipment, supplies and gases). Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 3 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6/23/2026
Date

Section 4: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Luria Therapeutics Holdings LLC

Corporation/Organization Name: Luria Therapeutics LLC

Mailing Address: 10411 Corporate Drive, Suite 108

City: Pleasant Prairie State: Wisconsin Zip: 53158

Telephone: (877) 587-4299 Email: statelicensing@luriapharma.com

Contact Person Name: James DeFranco

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	x	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 10: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale [a]Medical Products (medical devices, equipment, supplies, gases). (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Products (medical devices, equipment, supplies, gases), supply a copy of proof of insurance (NAC 639.6957).** The Medical Products wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 9)				
• **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20NRS%20639.500%20-%20Effective%2001.07.2026%20-%20Wholesaler%20-%20Post%20on%201.26.26.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Luria Therapeutics LLC
Facility Name

Nicole Shamoon
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

6/23/2026
Date

Board Use Only	Date Received: 8/6/26	Amount: $1,000 CK 5887

Outlook

Labeler Code Request Approved

From edrls@fda.hhs.gov <edrls@fda.hhs.gov>
Date Tue 4/21/2026 8:30 AM
To Nicole Shamoon <nicole.shamoon@luriapharma.com>

Current Date: 21-APR-2026
Labeler DUNS: 144956009
Labeler Name: Luria Therapeutics LLC
Labeler Code Assigned: 87628

The Food and Drug Administration (FDA) has assigned the above Labeler Code to the firm. However, the Labeler Code cannot be used in any drug listing submission until you have confirmed the assignment. To complete this process, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root ID and new version number with the original set ID and the appropriate effective time.

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

Once you have confirmed the assignment, this Labeler Code shall be used to propose the National Drug Code (NDC) for assignment to all drugs you manufacture or distribute for U.S. commercial distribution. The requirements regarding the assignment of an NDC is extensively discussed in Part 207.33 of Title 21 of the Code of Federal Regulations (CFR). The NDC for each drug must be submitted as part of drug listing information submitted to FDA.

Per section 510(j)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR Part 207 registrants that are required to register their establishment with FDA (or Private Label Distributors (PLD) acting as their authorized agent) must list each drug that it manufactures, repacks, relabels, or salvages for commercial distribution, including the appropriate NDC, no later than 3 calendar days after the initial registration of the establishment. Labeler name, physical address, email address and other contact information, type(s) of activities, and type(s) of drug(s) must be updated within 30 calendar days after any change to that information, § 207.33(c)(2). FDA uses this information for official communication regarding listing.

Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the FD&C Act or other applicable FDA regulations.

Note that receipt of this letter and assignment of an NDC does not denote approval of the establishment or the drug or any other drugs of the establishment, nor does it mean that the drug may be legally marketed.

For additional information please visit Drug Registration and Listing System or reply to this email (edrls@fda.hhs.gov).

Regards,

DRLB

FDA U.S. FOOD & DRUG ADMINISTRATION

LURIA
PHARMA

Description of Operations

Luria Therapeutics LLC ("Luria") is a Virtual Manufacturer of prescription drugs. Luria's products are not Controlled Substances. As a Virtual Manufacturer, Luria does not manufacture, distribute, or store drug product at their facility. Luria's products are manufactured by a Contract Manufacturer and will be distributed by a Third-Party Logistics Provider, who is licensed to ship pharmaceutical products into your state.
Hours of operation 9 AM to 5 PM Monday through Friday.

Luria Labeler Code: 87628

Contract Manufacturing

At no time does the Contract Manufacturer own the product, contract with Luria's customers, invoice, or sell Luria's product.

Patheon, part of Thermo Fischer Scientific
2100 Syntex Court
Mississauga, Canada ON L5N 7KP
FDA Establishment Number: 3000264888

Sharp Packaging Services, LLC
23 Carland Road
Conshohocken, PA 19428
FDA Establishment Number: 2518332

Third Party Logistics

Luria's Third Party Logistics (3PL) provider manages the storage and distribution of Luria's product into the commercial supply channels. Luria's records are stored at the 3PL:

Integrated Commercialization Solutions LLC
167 International Blvd., STE A
Brooks, KY 40109

Company Information

Luria Therapeutics LLC
10411 Corporate Drive, Suite 108
Pleasant Prairie, WI, 53158
(877) 587-4299
statelicensing@luriapharma.com

FEIN: 41-3191985
State of Formation: Delaware
Date Incorporated: 12/19/2025
File Number: 10445803

Ownership Information

Luria Therapeutics LLC is 100% owned by Luria Therapeutics Holdings LLC.

Parent Company: Luria Therapeutics Holdings LLC
Parent Company Address: 10411 Corporate Drive, Suite 108, Pleasant Prairie, WI, 53158
Parent Company Phone: (877) 587-4299
Parent Company FEIN: 41-3203487

Officers

Bryan Reiners, CEO
Business Address: 10411 Corporate Drive, Suite 108, Pleasant Prairie, WI, 53158
Business Phone: (877) 587-4299

Nicole Shamoon, Secretary
Business Address: 10411 Corporate Drive, Suite 108, Pleasant Prairie, WI, 53158
Business Phone: (877) 587-4299

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "LURIA THERAPEUTICS LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTEENTH DAY OF JULY, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.



C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

10445803 8300

SR# 20263763990

Authentication: 204560783

Date: 07-17-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

License Exemption

Luria Therapeutics, LLC is not required to hold a license in the state of Wisconsin, based on the following:

2. A corporate headquarters for a drug manufacturer, located in this state, does not need to be licensed as a manufacturer if the headquarters is not a facility where manufacturing occurs.

3. A drug manufacturer may retain title to prescription drugs distributed to pharmacies until the medications are actually sold to a consumer pursuant to a prescription order. The pharmacy laws in this state do not prohibit the business arrangement proposed.

The above can be referenced on the attached Wisconsin Pharmacy Examining Board provided document.

Wisconsin Department of Safety and Professional Services

Office Location: 4822 Madison Yards Way
Madison, WI 53705
Phone Number: (608) 266-2112

LicensE Portal: License.wi.gov
Email: dsps@wisconsin.gov
Website: http://dsps.wi.gov

PHARMACY EXAMINING BOARD

BUSINESS MODELS AND THE REQUIREMENTS FOR LICENSURE

(PHARMACY, PRESCRIPTION DRUG OR DEVICE DISTRIBUTOR AND DRUG MANUFACTURER)

Drug Manufacturers:

1. Drug or device manufacturing facilities which are located within the state of Wisconsin are required to obtain a manufacturer's license from the board.

2. A corporate headquarters for a drug manufacturer, located in this state, does not need to be licensed as a manufacturer if the headquarters is not a facility where manufacturing occurs.

3. A drug manufacturer may retain title to prescription drugs distributed to pharmacies until the medications are actually sold to a consumer pursuant to a prescription order. The pharmacy laws in this state do not prohibit the business arrangement proposed.

4. No distributor's license would be required for an out-of-state manufacturing facility that engages in the wholesale distribution of prescription drugs in this state from that manufacturing facility.

Prescription Drug and/or Device Distributors:

1. A distributor's license authorizes a facility to sell prescription drugs or devices to pharmacists, pharmacies, researchers, hospitals, authorized agents of the federal government and other distributors. A distributor's license does not authorize a facility to dispense prescription drugs directly to patients pursuant to a prescriber's prescription order. Dispensing directly to patients under a prescription order requires a pharmacy license.

2. Out-of-state or in-state wholesale distributors of prescription drugs are required to obtain a distributor's license in Wisconsin for each facility from which the prescription drugs are distributed.

3. A prescription device distributor does not need to be registered with the Food and Drug Administration, if it is not a manufacturer or initial importer **and** distributes a device from the original location of the manufacturer to the person who is making the final delivery or sale of the device to the ultimate consumer and/or user. A Wisconsin prescription device distributor license is still needed.

Out-of-State Pharmacies:

Effective April 13, 2006

1. This state requires a Wisconsin pharmacy license be obtained by pharmacies licensed in another state which dispense prescription medications, including schedule II controlled substances, by mail or other delivery to patients in this state.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. EACX4058628

Application/License No. _____

Luria Therapeutics LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 10411 Corporate Drive, Suite 108, Pleasant Prairie, WI 53158 (Address of Applicant/Principal), as PRINCIPAL, and Endurance Assurance Corporation (Surety Company), a corporation organized under the laws of the state of Delaware (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 4 Manhattanville Road 3rd Floor, Purchase, NY 10577 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 29, 2026 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 30 day of June, 20 26.

APPLICANT/PRINCIPAL
Luria Therapeutics LLC

Authorized Representative

SURETY COMPANY
Endurance Assurance Corporation

Surety Company's Representative

Loretta Jones, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Cindy Johnson

Witness Bonnie Rice

Countersigned by:

Nevada Resident Agent
Loretta Jones NV Non-resident license 527233

Posted February 20, 2020

SOMPO INTERNATIONAL
INSURANCE

POWER OF ATTORNEY

2640

KNOW ALL BY THESE PRESENTS, that **Endurance Assurance Corporation**, a Delaware corporation ("EAC"), **Endurance American Insurance Company**, a Delaware corporation ("EAIC"), **Lexon Insurance Company**, a Texas corporation ("LIC"), and/or **Bond Safeguard Insurance Company**, a South Dakota corporation ("BSIC"), each, a "Company" and collectively, "**Sompo International**," do hereby constitute and appoint: Loretta Jones of Knoxville TN

as true and lawful Attorney(s)-In-Fact to make, execute, seal, and deliver for, and on its behalf as surety or co-surety; bonds and undertakings given for any and all purposes, also to execute and deliver on its behalf as aforesaid renewals, extensions, agreements, waivers, consents or stipulations relating to such bonds or undertakings provided, however, that no single bond or undertaking so made, executed and delivered shall obligate the Company for any portion of the penal sum thereof in excess of the sum of **One Hundred Million Dollars ($100,000,000.00)**.

Such bonds and undertakings for said purposes, when duly executed by said attorney(s)-in-fact, shall be binding upon the Company as fully and to the same extent as if signed by the President of the Company under its corporate seal attested by its Corporate Secretary.

This appointment is made under and by authority of certain resolutions adopted by the board of directors of each Company by unanimous written consent effective the 30th day of March, 2023 for BSIC and LIC and the 17th day of May, 2023 for EAC and EAIC, a copy of which appears below under the heading entitled "Certificate".

This Power of Attorney is signed and sealed by facsimile under and by authority of the following resolution adopted by the board of directors of each Company by unanimous written consent effective the 30th day of March, 2023 for BSIC and LIC and the 17th day of May, 2023 for EAC and EAIC and said resolution has not since been revoked, amended or repealed:

RESOLVED, that the signature of an individual named above and the seal of the Company may be affixed to any such power of attorney or any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signature or seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN WITNESS WHEREOF, each Company has caused this instrument to be signed by the following officers, and its corporate seal to be affixed this 25th day of May, 2023.

Endurance Assurance Corporation
By: Richard M Appel
Richard Appel; SVP & Senior Counsel

Endurance American Insurance Company
By: Richard M Appel
Richard Appel; SVP & Senior Counsel

Lexon Insurance Company
By: Richard M Appel
Richard Appel; SVP & Senior Counsel

Bond Safeguard Insurance Company
By: Richard M Appel
Richard Appel; SVP & Senior Counsel

ACKNOWLEDGEMENT

On this 25th day of May, 2023, before me, personally came the above signatories known to me, who being duly sworn, did depose and say that he/they is/are officer of each of the Companies; and that he executed said instrument on behalf of each Company by authority of his office under the by-laws of each Company.

By: Amy Taylor
Amy Taylor, Notary Public – My Commission Expires 3/9/27

CERTIFICATE

I, the undersigned Officer of each Company, DO HEREBY CERTIFY that:

1. That the original power of attorney of which the foregoing is a copy was duly executed on behalf of each Company and has not since been revoked, amended or modified; that the undersigned has compared the foregoing copy thereof with the original power of attorney, and that the same is a true and correct copy of the original power of attorney and of the whole thereof;
2. The following are resolutions which were adopted by the board of directors of each Company by unanimous written consent effective 30th day of March, 2023 for BSIC and LIC and the 17th day of May, 2023 for EAC and EAIC and said resolutions have not since been revoked, amended or modified:

   "RESOLVED, that each of the individuals named below is authorized to make, execute, seal and deliver for and on behalf of the Company any and all bonds, undertakings or obligations in surety or co-surety with others: RICHARD M. APPEL, MATTHEW E. CURRAN, MARGARET HYLAND, SHARON L. SIMS, CHRISTOPHER L. SPARRO,

   and be it further

   RESOLVED, that each of the individuals named above is authorized to appoint attorneys-in-fact for the purpose of making, executing, sealing and delivering bonds, undertakings or obligations in surety or co-surety for and on behalf of the Company."
3. The undersigned further certifies that the above resolutions are true and correct copies of the resolutions as so recorded and of the whole thereof.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the corporate seal this 30th day of June, 20 26.

By:
Daniel S. Lurie, Secretary

NOTICE: U. S. TREASURY DEPARTMENT'S OFFICE OF FOREIGN ASSETS CONTROL (OFAC)

No coverage is provided by this Notice nor can it be construed to replace any provisions of any surety bond or other surety coverage provided. This Notice provides information concerning possible impact on your surety coverage due to directives issued by OFAC. **Please read this Notice carefully.**

The Office of Foreign Assets Control (OFAC) administers and enforces sanctions policy, based on Presidential declarations of "national emergency". OFAC has identified and listed numerous foreign agents, front organizations, terrorists, terrorist organizations, and narcotics traffickers as "Specially Designated Nationals and Blocked Persons". This list can be located on the United States Treasury's website – https://www.treasury.gov/resource-center/sanctions/SDN-List.

In accordance with OFAC regulations, if it is determined that you or any other person or entity claiming the benefits of any coverage has violated U.S. sanctions law or is a Specially Designated National and Blocked Person, as identified by OFAC, any coverage will be considered a blocked or frozen contract and all provisions of any coverage provided are immediately subject to OFAC. When a surety bond or other form of surety coverage is considered to be such a blocked or frozen contract, no payments nor premium refunds may be made without authorization from OFAC. Other limitations on the premiums and payments may also apply.

ENDURANCE ASSURANCE CORPORATION
Balance Sheet - Statutory - Basis
December 31, 2025

Assets:		
Bonds	$	10,854,185,620
Preferred stocks		27,363,642
Common stocks		1,960,798,187
Cash, cash equivalents, and short-term investments		395,379,326
Other invested assets		551,637,436
Receivables for securities		4,223,627
Total cash and invested assets		**13,793,587,838**
Agents' balances or uncollected premiums		3,665,995,301
Reinsurance recoverable on loss and loss adjustment expense payments		828,945,765
Funds held by or deposited with reinsured companies		127,770,761
Investment income due and accrued		100,619,761
Net deferred tax asset		224,974,102
Receivables from parent, subsidiaries and affiliates		111,554,007
Other assets		428,555,658
Total admitted assets	$	**19,282,003,193**
Liabilities:		
Loss and loss adjustment expenses	$	8,052,879,038
Reinsurance payable on paid loss and loss adjustment expenses		565,324,592
Commissions payable, contingent commissions and other similar charges		4,799,052
Other expenses		47,161,931
Taxes, licenses and fees (excluding federal and foreign income taxes)		47,147,613
Unearned premiums		3,089,355,684
Advanced premium		2,738,073
Ceded reinsurance premiums payable		1,395,006,718
Current federal and foreign income taxes		70,878,624
Funds held by company under reinsurance treaties		127,321,431
Amounts withheld or retained by company for account of others		600,968,753
Remittances and items not allocated		103,410,529
Provision for reinsurance		24,596,927
Payable to parent, subsidiaries and affiliates		451,681,563
Payable for securities		40,796,113
Other liabilities		109,029,708
Total liabilities		**14,733,096,349**
Capital and surplus:		
Common capital stock		5,000,000
Gross paid in and contributed surplus		3,480,137,280
Unassigned funds (surplus)		1,062,480,277
Aggregate write-ins for special surplus funds		1,289,287
Total capital and surplus		**4,548,906,844**
Total liabilities and capital and surplus	$	**19,282,003,193**

I, Hana Entela, Treasurer of Endurance Assurance Corporation (the "Company") do hereby certify that to the best of my knowledge and belief, the foregoing is a full and true Statutory Statement of Admitted Assets, Liabilities, Capital and Surplus of the Company as of December 31, 2025 prepared in conformity with accounting practices prescribed or permitted by the State of Delaware Department of Insurance. The foregoing statement should not be taken as a complete statement of financial condition of the Company. Such a statement is available upon request at the Company's office located at 4 Manhattanville Road, Purchase, NY 10577.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of the Company at Purchase, New York.

Hana Entela

Subscribed and sworn to before me this 19th day of March, 2026

Fiona McNamara

Fiona McNamara
STATE OF NEW YORK
NOTARY PUBLIC
Qualified in Rockland County
01MC5081895
MY COMMISSION EXPIRES 07/14/2029

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Luria Therapeutics LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 10411 Corporate Drive, Suite 108

City Pleasant Prairie State WI Zip 53158

Mailing Address (if different from physical address) 10411 Corporate Drive, Suite 108

City Pleasant Prairie State Wisconsin Zip 53158

Telephone (877) 587-4299 Website _____

Licensing Company Email statelicensing@luriapharma.com

Section 2: Personal Information

First James Middle Paul Last DeFranco

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 10411 Corporate Drive, Suite 108

City Pleasant Prairie State Wisconsin Zip 53158

Telephone (877) 587-4299 Email james.defranco@luriapharma.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UW Parkside		09/00-8/02	
Address	City	State	Zip
900 Wood Road	Kenosha	WI	53144
Diploma/Degree obtained, if any			
BS Molecular Biology			

School Name		From - To (MM/YY – MM/YY)	
UW Madison		09/97-12/99	
Address	City	State	Zip
1308 W Dayton Street	Madison	WI	53144
Diploma/Degree obtained, if any			
None			

School Name		From - To (MM/YY – MM/YY)	
Tremper High School		09/94-06/97	
Address	City	State	Zip
8560 26th Avenue	Kenosha	WI	53143
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/19-Present	[redacted]	Pleasant Prairie	WI	[redacted]
05/14-10/19	[redacted]	Pleasant Prairie	WI	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Luria Therapeutics LLC			5/26-Present
Business Address	**City**	**State**	**Zip**
10411 Corporate Drive, Suite 108	Pleasant Prairie	WI	53158
Phone	**Title**	**Number of Employed Hours**	
(877) 587-4299	Sr Direction, Supply Chain	160	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
TerSera Therapeutics LLC			02/21-5/26
Business Address	**City**	**State**	**Zip**
520 Lake Cook Road, Suite 500	Deerfield	IL	60015
Phone	**Title**	**Number of Employed Hours**	
(847) 739-0940	Director, Supply Chain	11,040	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

James DeFranco

[redacted]

SUPPLY CHAIN MANAGEMENT PROFESSIONAL

- Senior Supply Chain Operations Leader with extensive experience driving performance and transformation across global pharmaceutical manufacturing networks, encompassing internal operations, third-party providers, and contract manufacturing organizations
- Enterprise Supply Chain leader recognized for driving capacity optimization and operational excellence through disciplined scheduling, robust forecast analytics, comprehensive budget reporting, and rigorous schedule adherence metrics
- Senior Director with deep project management expertise across critical supply chain initiatives, including API sourcing and allocation, commodities management, product transfers and launches, and disciplined inventory write-off analysis
- Unique combination of Quality Program Management, SAP Master Data, Project Management, Logistics, and a vast knowledge of Supply Planning including budgeting, new product launches / transfers, acquisitions/divestures
- Extensive experience leading supply and trade negotiations, consistently generating multimillion-dollar annual cost savings while strengthening strategic supplier partnerships

•Sales & Operations Planning Leadership • Production Planning, Scheduling, & Capacity Management •New Product Launches & Technology Transfers •Supply Chain Analytics & Executive Reporting • Budget Development & Financial Management • Commercial & Cross-Functional Partnership • Program & Project Management •Supplier Qualification, Vendor & CMO Management • Third-Party Logistics Oversight • Serialization & Regulatory Compliance (DSCSA) • Enterprise Risk Management & Mitigation • Order to Cash & Order Fulfillment Execution

PROFESSIONAL EXPERIENCE

LURIA THERAPEUTICS LLC
Senior Director, Supply Chain **May 4, 2026 – Present**

- Build and manage Contract Manufacturing Organization (CMO) relationships, including:
  - Reporting monthly production forecasts to CMOs
  - Leading contract negotiations
  - Escalating potential supply risks to Executive Management
  - Monitoring and tracking CMO on time delivery and performance metrics
- Maintain full accountability for Third-Party Logistics (3PL) operations and performance
  - Inventory Management
  - Order Processing
  - Inventory Replenishments
  - New Product Set up and onboarding
  - Leadership of Quarterly Business Reviews (QBRs)
- Conduct the annual Supply Chain Risk Assessment
- Serve as Subject Matter Expert (SME) for Drug Serialization
  - Ensuring serialization compliance, including GS1 GTIN code creation
  - Managing the TraceLink system
  - Overseeing 3PL management of EPCIS data transmission
- Lead Executive S&OP monthly meetings
- Design, implement, and manage a sustainable monthly planning, forecasting, and purchasing process
  - Development of the planning model
  - Approval of direct product purchase orders
  - Monthly Supply Chain management reviews
- Oversee logistics management for APIs, finished goods, and analytical samples
- Lead Trade Operations and CMO relationship management activities
- Direct Supply Chain activities for mergers, acquisitions, and divestitures

TERSERA THERAPEUTICS LLC
Senior Director, Supply Chain **Feb 22, 2021 – May 1, 2026**

- Develop, track, and report $50M budget consisting of inventory spend, 3PL services, stability, and distribution
  - Coordinate with Finance on estimated monthly/yearly spending
- Build and Manage CMO relationship
  - Report current monthly production forecast to CMO
  - Contract negotiation
  - Escalate any protentional Supply Risk to Executive Management
  - Track CMO on time/delivery metrics
- Full accountability of 3PL Activities and Performance
  - Inventory Management
  - Order Processing
  - Inventory Replenishments
  - New Product Set up
  - Leading Quarterly Business Reviews
- Complete yearly Supply Chain Risk Assessment
- Drug Serialization SME / DSCSA Readiness
  - Serialization compliance including GS1 GTIN code creation
  - TraceLink System Management
  - 3PL Management of EPCIS Data
- Facilitate cross functional weekly meetings with QA, Regulatory, and Commercial to ensure supply continuity
- Lead Executive S&OP monthly meetings
- Create and manage a sustainable monthly planning, forecasting, and purchasing process
  - Development of the planning model, supplier forecast submission, direct product purchase order approval, and monthly management review with Supply Chain
- Manage a team consisting of Sr. Supply Chain Analyst and Sr. Manager, Purchasing and Supply Chain Operations
- Logistics Management for API, Finished Goods, and Analytical Samples
- Trade and CMO Relationship Management
- Lead Supply Chain activities for acquisitions / divestures

PFIZER, INC., LAKE FOREST, IL **Jun 1, 2016 – Feb 19, 2021**
Sterile Injectable Supply Chain Manager

- Brand Supply Leader for Heparin and Precedex.
  - Coordinating supply between three manufacture sites on multiple NDC's
  - Allocating limited API between Rocky Mount and Vizag
  - Providing weekly updates to Senior Management and Commercial
  - Completed AFW to secure $28M additional API for Kalamazoo in 2020
  - Prepare and Facilitate Monthly S&OP for Heparin and Precedex.
- Manage the SI Transition from Rocky Mount / McPherson to the Vizag Manufacturing plant (annualized production volume of 225 million plus units). Ensuring proper weeks of stock and no supply interruption during transition
- Manage Pfizer ANDA transfer to CMO ANDA (six molecules)
- Oversaw the Oncology transfer from PGS Melbourne to the ZHOPL MFG site, 50 SKUs successfully transferred
- Lead all supply chain activities Gerresheimer Molded Glass supply disruption
  - Directed all glass resorting priorities to Assempak resorting facility
  - Obtained and present weekly supply information to the Senior Leadership and EVP
  - Coordinated new glass production needs along with production from an alternate glass supplier to reduce supply gaps
  - Tracked and measured current and future glass supply versus manufacturing needs
- Facilitate weekly meetings with Portfolio Managers on any supply issue current or future
- Escalate any potential supply/manufacturing issues to Commercial, Upper Management, S&OP, and Drug Shortage Teams. Present the History, Issue, Next Steps, and Recovery
- Plan (Above Site Planning; MPS) six manufacturing lines at Rocky Mount, NC Facility; 170 SKUs for 260 million units annually; report a 24-month rolling plan and budget reporting/adherence
- Coordinate release schedules with the manufacture site, medically necessary / Drug shortage items
- Point of Contact (Power User) for Legacy Hospira Supply Chain on the Business Object (BOBJ) Reporting system
  - Manage the Master Data correction/updates for all Legacy Hospira Sites
  - Train Legacy Hospira coworkers on new reporting system
- Report all volume and forecast changes during Monthly Plan of Record Meeting
  - Provide clear and concise reasoning for all changes to plant yearly budgets

HOSPIRA, A PFIZER COMPANY, LAKE FOREST, IL **Nov 1, 2013 – Jun 1, 2016**
Quality Program Manager

- Interfaced with other departments to manage/facilitate new product launches. Developed the strategies and systems to position inventory to be first to market
- Managed CAPA and Investigations in Trackwise related to Supply Chain and Quality
- Audited Public Warehouses and Hospira Distribution Centers
- Managed Corporate Quality Hold / Dispositions and support Global Recall System
- Initiated, managed, and facilitated quality system improvement projects
- Performed validations and qualifications in accordance with corporate policy
- Researched, interpreted, and acted on current and proposed regulations (domestically and internationally) that impacted supply chain operations
- Established quality systems and procedures that minimize quality cost and provide a high level of compliance
- Developed operational procedures and training material
- Managed the quality improvement initiatives that are strategic to the business

HOSPIRA, A PFIZER COMPANY LAKE FOREST, IL **Sept 1, 2010 – Nov 1, 2013**
Senior Planning Specialist

- Planner for four Hospira Plants: Zydous Hospira Oncology; Hospira India; Zagreb, Croatia (2010-2011); and Rocky Mt., NC. (2011-2013)

HOSPIRA, A PFIZER COMPANY, LAKE FOREST, IL **Sept 10, 2005 – Sept 1, 2010**
Supply Chain Analyst (Centralized Material Master Group)

HEXION SPECIALITY CHEMICALS FNA LAWTER INT AN RSM COMPANY **Mar 1, 2000 – Sept. 7, 2005**
QC Laboratory Technician / SAP Master Data Maintainer

COMPUTER SKILLS

ERP Software	ERP, SAP R/3, APO, SAP BW, SAP DMS
Applications/Tools	MS-Office (Excel, Power Point, Project, Word, Visio, Access), BOBJ, Steelwedge, Tableau, Oscar, NetSuite

EDUCATIONAL QUALIFICATIONS

Bachelor of Science, Molecular Biology **Aug 2002**
University of Wisconsin Parkside

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		x
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, James DeFranco, **certify that as the designated representative for**

Luria Therapeutics LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JD I am at least 21 years of age;
3. JD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

James DeFranco

Print Name (First, Last)

JD

Original Signature (electronic, copies or stamps not accepted)

10/23/2016

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

James DeFranco

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

06/25/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Illinois, ss. County of Lake

I, James DeFranco, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

06/25/2026

Date

Subscribed and Sworn to before me this 25 day of June 2026

Notary Public Signature

OFFICIAL SEAL
SHIRLEY R FUGIEL
NOTARY PUBLIC, STATE OF ILLINOIS
My Commission Expires 8/6/26

(Seal)

LURIA

July 13, 2026

Luria Therapeutics LLC
10411 Corporate Drive, Suite 108
Pleasant Prairie, WI 53158

RE: Section 10: List of Employees, agent, etc.

To Whom It May Concern:

This letter is provided in support of the licensure of Luria Therapeutics LLC and serves to identify the list of individuals associated with the facility location of **10411 Corporate Drive, Suite 108, Pleasant Prairie, Wisconsin 53158** (employees, agent, independent contractor, consultant, etc).

Access to the facility is restricted to authorized personnel whose responsibilities require entry into the premises. The following individuals have been designated with authorized access:

Name
James DeFranco
Yeime Martich
Anne Guttschow
Nicole Shamoon
Bryan Reiners

4X

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Mandos, LLC

Physical Address: 50 Milk Street 11th floor

City: Boston State: MA Zip: 02109

Mailing Address (if different from physical address): 50 Milk Street 11th floor

City: Boston State: Massachusetts Zip: 02109

Telephone: (503) 502-0078 Website: https://mandoshealth.com/about-us

Name of Designated Representative (DR): Bennett Smith

Licensing Company Email: statelicense@berentx.com DR Email: bsmith@berentx.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Infusion Clinics, Specialty Distributors, and Specialty Pharmacies		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No suppliers sold, dispensed, or distributed to within the last year.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Beren Therapeutics P.B.C.

Corporation/Organization Name: Mandos, LLC

Mailing Address: 50 Milk Street 11th floor

City: Boston State: Massachusetts Zip: 02109

Telephone: (805) 917-6315 Email: contact@berentx.com

Contact Person Name: Peter Cicala

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____ Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	x	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Mandos, LLC

Facility Name

Peter Cicala

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

2/3/2026

Date

Board Use Only	Date Received: _____	Amount: _____

From: edrls@fda.hhs.gov
To: Jennifer Spinella
Subject: Labeler Code Request Approved
Date: Friday, November 14, 2025 4:43:12 AM

Current Date: 14-NOV-2025
Labeler DUNS: 138389827
Labeler Name: Mandos LLC
Labeler Code Assigned: 87230

The Food and Drug Administration (FDA) has assigned the above Labeler Code to the firm. However, the Labeler Code cannot be used in any drug listing submission until you have confirmed the assignment. To complete this process, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root ID and new version number with the original set ID and the appropriate effective time.

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

Once you have confirmed the assignment, this Labeler Code shall be used to propose the National Drug Code (NDC) for assignment to all drugs you manufacture or distribute for U.S. commercial distribution. The requirements regarding the assignment of an NDC is extensively discussed in Part 207.33 of Title 21 of the Code of Federal Regulations (CFR). The NDC for each drug must be submitted as part of drug listing information submitted to FDA.

Per section 510(j)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR Part 207 registrants that are required to register their establishment with FDA (or Private Label Distributors (PLD) acting as their authorized agent) must list each drug that it manufactures, repacks, relabels, or salvages for commercial distribution, including the appropriate NDC, no later than 3 calendar days after the initial registration of the establishment. Labeler name, physical address, email address and other contact information, type(s) of activities, and type(s) of drug(s) must be updated within 30 calendar days after any change to that information, § 207.33(c)(2). FDA uses this information for official communication regarding listing.

Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the FD&C Act or other applicable FDA regulations.

Note that receipt of this letter and assignment of an NDC does not denote approval of the establishment or the drug or any other drugs of the establishment, nor does it mean that the drug may be legally marketed.

For additional information please visit Drug Registration and Listing System or reply to this email (edrls@fda.hhs.gov).

Mandos LLC® By Beren Therapeutics, a Public Benefit Corporation

Description of Operations

Mandos, LLC is a Virtual Manufacturer of prescription drugs. Mandos, LLC's products are not Controlled Substances. As a Virtual Manufacturer, Mandos, LLC does not manufacture, distribute, or store drug product at its facility. Mandos, LLC's products are manufactured by a Contract Manufacturer and will be distributed by a Third-Party Logistics Provider, who is licensed to ship pharmaceutical products into your state.

Mandos, LLC has 1 employee working on site during normal business hours with Hours of operation 9 AM to 5 PM Monday through Friday. Mandos, LLC's facility square footage is 300 sq. ft.

Mandos, LLC Labeler Code: 87230

Contract Manufacturing

At no time does the Contract Manufacturer own the product, contract with Mandos, LLC's customers, invoice, or sell Mandos, LLC's product.

Alcami Corporation
4221 Faber Place Dr
Charleston, SC 29405
FDA Establishment Number: 1000110990

AndersonBrecon Inc. DBA PCI Pharma Services
4545 Assembly Dr.
Rockford, IL 61109
FEI: 1421377

Third Party Logistics

Mandos, LLC's Third Party Logistics (3PL) provider manages the storage and distribution of Mandos, LLC's product into the commercial supply channels. Mandos, LLC's records are stored at the 3PL:

Integrated Commercialization Solutions, LLC
167 International Blvd Suite A
Brooks, KY 40109

Mandos LLC® By Beren Therapeutics, a Public Benefit Corporation

Company Information

Mandos LLC
50 Milk St., 11th floor
Boston, MA 02109
(503) 502-0078
Website: https://mandoshealth.com/about-us
Facility E-mail: statelicense@berentx.com

FEIN: 87-0970516
State of Formation: DE
Date Incorporated: 4/26/2021
File Number: 5859896

Ownership Information

Mandos, LLC is 100% owned by Beren Therapeutics P.B.C.

Parent Company Address: 2101 Corporate Center Drive #100, Thousand Oaks, CA 91320
Parent Company Phone: (805) 917-6315
Parent Company FEIN: 84-4647816

Sole Officer

Peter Cicala, President & General Counsel
Business Address: 2101 Corporate Center Dr., Suite 100
Business Phone: (805) 917-6315

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "MANDOS LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINTH DAY OF MARCH, A.D. 2026.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 203285321

Date: 03-09-26

5859896 8300

SR# 20261070322

You may verify this certificate online at corp.delaware.gov/authver.shtml

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

Mandos, LLC
50 Milk Street, 11th Floor
Boston, MA 02109

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: VIR200155

Type: Virtual Manufacturer

Issue Date: 03/17/2026

Expiration Date: 03/17/2027

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 101958783

Application/License No. _____

Mandos, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 50 Milk St, Floor 11 Boston, MA 02109 (Address of Applicant/Principal), as PRINCIPAL, and Merchants National Bonding, Inc. (Surety Company), a corporation organized under the laws of the state of Iowa (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 6700 Westown Parkway, West Des Moines, IA 50266 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on July 28, 2026 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 28th day of July, 2026.

APPLICANT/PRINCIPAL

Mandos, LLC

Authorized Representative

SURETY COMPANY

Merchants National Bonding, Inc.
Surety Company's Representative

Valerie Garcia, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Nerissa Bartolome

Witness Rossio Polio

Countersigned by:

Nevada Resident Agent Not Applicable

LP 4229 NV (5/21)

MERCHANTS BONDING COMPANY™

POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa, and MERCHANTS NATIONAL INDEMNITY COMPANY , an assumed name of Merchants National Bonding, Inc., (herein collectively called the "Companies") do hereby make, constitute and appoint, individually,

Valerie Garcia

their true and lawful Attorney(s)-in-Fact, to sign its name as surety(ies) and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the By-Laws adopted by the Board of Directors of the Companies.

"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-in-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and authority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner - Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 28th day of July , 2026 .

MERCHANTS BONDING COMPANY (INCORPORATED -o- 1933) (MUTUAL)
MERCHANTS NATIONAL BONDING, INC. (INCORPORATED -o- 2003)
MERCHANTS NATIONAL INDEMNITY COMPANY (CALIFORNIA)

MERCHANTS BONDING COMPANY (MUTUAL)
MERCHANTS NATIONAL BONDING, INC.
MERCHANTS NATIONAL INDEMNITY COMPANY

By Larry Taylor
President

STATE OF IOWA
COUNTY OF DALLAS ss.
On this 28th day of July 2026 , before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL), MERCHANTS NATIONAL BONDING, INC., and MERCHANTS NATIONAL INDEMNITY COMPANY; and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.

NOTARIAL SEAL IOWA
Penni Miller
Commission Number 787952
My Commission Expires
January 20, 2027

Notary Public

(Expiration of notary's commission does not invalidate this instrument)

I, Elisabeth Sandersfeld, Secretary of MERCHANTS BONDING COMPANY (MUTUAL), MERCHANTS NATIONAL BONDING, INC., and MERCHANTS NATIONAL INDEMNITY COMPANY do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 28th day of July , 2026 .

MERCHANTS BONDING COMPANY (INCORPORATED -o- 1933) (MUTUAL)
MERCHANTS NATIONAL BONDING, INC. (INCORPORATED -o- 2003)
MERCHANTS NATIONAL INDEMNITY COMPANY (CALIFORNIA)

Secretary

POA 0018 (5/25)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Mandos, LLC

Pharmacy/Wholesaler License # (if applicable)

Physical Address 50 Milk Street 11th floor

City Boston State MA Zip 02109

Mailing Address (if different from physical address) 50 Milk Street 11th floor

City Boston State Massachusetts Zip 02109

Telephone (503) 502-0078 Website https://mandoshealth.com/about-us

Licensing Company Email statelicense@berentx.com

Section 2: Personal Information

First Bennett Middle Mesrovbe Last Smith

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 50 Milk Street 11th floor

City Boston State Massach Zip 02109

Telephone (503) 502-0078 Email bsmith@berentx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Washington		09/04-05/07	
Address	City	State	Zip
1410 NE Campus Parkway	Tacoma	WA	98195
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
College of Idaho		09/98-05/02	
Address	City	State	Zip
2112 Cleveland Blvd	Caldwell	ID	83605
Diploma/Degree obtained, if any			
BS, Biology			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/19-Present	[redacted]	Watertown	MA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Mandos, LLC			05/25-Present
Business Address	**City**	**State**	**Zip**
50 Milk Street 11th floor	Boston	MA	02109
Phone	**Title**	**Number of Employed Hours**	
(503) 502-0078	SVP Commercial	40	
Description of Duties			
See attached Resume.			

Business Name			From - To (MM/YY – MM/YY)
Orchard Therapeutics			10/23-05/25
Business Address	**City**	**State**	**Zip**
101 Seaport Boulevard, 7th Floor	Boston	MA	02210
Phone	**Title**	**Number of Employed Hours**	
+44 203-808-8286	SVP, General Manager, North America	40	
Description of Duties			
See attached Resume.			

Business Name			From - To (MM/YY – MM/YY)
Akebia Therapeutics			01/18-10/23
Business Address	**City**	**State**	**Zip**
245 First Street, Suite 1400	Cambridge	MA	02142
Phone	**Title**	**Number of Employed Hours**	
617-871-2098	SVP, Commercial	40	
Description of Duties			
See attached Resume.			

Business Name			From - To (MM/YY – MM/YY)
Regeneron Healthcare Solutions			01/16-01/18
Business Address	**City**	**State**	**Zip**
777 Old Saw Mill River Road	Tarrytown	NY	10591
Phone	**Title**	**Number of Employed Hours**	
(914) 847-7000	Senior Director, US & Global Market Access	40	
Description of Duties			
See attached Resume.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

BENNETT MESROVBE SMITH, MBA

[redacted]

Commercial & Market Access Transformational Leader in Healthcare

Senior leader with a successful track record of launching blockbuster brands and revitalizing late-in-market assets through architecting and implementing innovative Market Access, Marketing and Sales initiatives within the Pharmaceutical/Biotech industries. Build commercial functions and assemble teams and departments from the ground up. A results-driven and strategic leader overseeing all commercial functions with full P&L responsibility and staff management in various therapeutic areas.

Core Competencies & Executive Highlights

- **Market Access & Commercial Expertise Driving Growth & Revenue:**
  - **Beren:** Built full commercialization capability for first product launch in neurodegenerative disorder; inclusive of supply chain, commercial, and medical affairs.
  - **Orchard:** Delivered US launch excellence and full commercial build supporting a curative gene therapy in rare disease.
  - **Akebia:** Achieved largest AURYXIA revenue increase in 8th year of commercialization through optimized commercial strategy and execution.
  - **Regeneron:** Shifted access strategy, improving Commercial and Medicare approval rates from 20% to ~75% for PRALUENT® after 1 year on market.
  - **Novo Nordisk:** Achieved double-blockbuster success for Victoza® launch in the U.S. without cannibalizing diabetes franchise.
- **Broad Managed Markets Channel Experience:** Commercial and Government (Medicare and Medicaid) Health Plans, PBMs, Employers, State / Federal government, GPOs, LTC, HS/IDNs, Employers, and Trade.
- **Transformational Leadership:** Proven record of recruiting and coalescing world-class Sales, Market Access, and Patient Access teams around new or realigned strategies with successful execution made possible by nurturing cultures where people feel they belong and can thrive and advance.

Leadership Experience

BEREN THERAPEUTICS, BOSTON, MA — **MAY 2025 – PRESENT**
MANDOS LLC, BOSTON, MA

SENIOR VICE PRESIDENT, COMMERCIAL

Brought into the executive team to build global commercialization capabilities for first product launch for a private, biotech company with anticipated US launch in 2026; EU launch in 2028

- **Lead external engagements with key investors for Series A and Structured Credit Financing** Raised sufficient capital to fund US commercialization and global expansion on a path to self-sustainability by 2027
- **Built high-performing functions across commercial, medical affairs, corporate communications, and supply chain** icore infrastructure for data unveiling, first scientific publications, data and insights generation, brand planning, investments to outperform launch.
- **Architected Go to Market strategy and execution** Identified key sites, KOLs, and treaters for early engagement in the USand Global to support a scalable model to retain rights and build a fully integrated biotech
- **Lead enterprise change management from R&D focused, clinical organization to shift enterprise wide capabilities to support commercialization** Lead cross functional launch planning with all enterprise functions, building ways of workingand systems that support the commercial needs for launch..
- **Developed growth strategies for adjacent indications,** Lead indication expansion with high POS and commercial value toadd accretive catalyst that will shift enterprise valuation in our 2030 vision

ORCHARD THERAPEUTICS, BOSTON, MA — **OCT 2023 – MAY 2025**

SENIOR VICE PRESIDENT, GENERAL MANAGER, NORTH AMERICA

Brought in to lead Orchard's (a subsidiary of Kyowa Kirin) first U.S. Commercial launch for first-in-class cell and gene therapy for ultra-rare pediatric condition.

- **Outperformed launch expectations for patient lead identification and new patient starts.** 120% commercial performance on new patient leads and exceeded new patient starts by 125%, leading to strong revenue performance.

- **Built high-performing team of 9 in 2.5 months** inclusive of Marketing, Patient Services, Market Access, and Advanced Therapy Account Management. Lead site qualification and certification. Built Government Affairs and Public Policy teams.
- **Created commercial analytics strategy for early diagnosis,** working cross-functionally with Medical to determine variables for diagnosis using data analytics and real-world claim surveillance, successfully generating leads across the U.S.
- **Architected Go to Market strategy and execution.** Qualify and choose treatment centers and ensure market access pull through for high-value cell therapy solidifying value proposition with ICER endorsed price.
  - Identify and partner with MLD experts, key Neurologists, Geneticists, referral centers and leading children's hospitals including CHOP, Stanford, Boston Children's, CHOA, UCSF, Primary Children's, UMN, and Lurie Children's.
- **Developed & launched PR strategy,** using traditional and non-traditional media to share customer stories to support grassroots efforts, hospital outreach, and legislative efforts for Newborn screening, and access opportunities.

AKEBIA THERAPEUTICS, CAMBRIDGE, MA 2018 – 2023

SENIOR VICE PRESIDENT, COMMERCIAL ('22 – '23)

Led integrated commercial functions including Marketing, Sales, Market Access, Pricing and Contracting, Trade and Rebate Operations, Commercial Analytics and Patient Services. Key member of the Executive Leadership Team overseeing incentive compensation, sales force sizing and commercial design.

- **Revamped contracting strategy leading to 25% YOY growth.** Achieved largest AURYXIA revenue increase through optimized commercial strategy and execution in 8th year of commercialization.
  - Optimized access and minimized gross-to-net impact for in-line asset for organized customers (dialysis providers), payer formulary, rebate and distribution agreements.
- **Led successful rebate concessions negotiations** with Part D plans after CMS imposed an indication-based prior authorization, yielding gross to net savings of $80-100M through LOE.
- **Rearchitected sales force strategy realizing $20M in yearly savings.** Reduced Sales team by more than 50% while growing revenue by designing and transitioning the organization to an account-based commercial model to improve demand generation with high-value customers, and a key account focus.
- **Led Business Development and Commercial strategy.** Implemented pipeline and LCM commercial strategy and assessment, facilitated R&D prioritization and Business Development execution for both out-licensing and in-licensing opportunities.

SENIOR VICE PRESIDENT, MARKETING, MARKET ACCESS AND PATIENT SERVICES ('21 – '22)

Led Marketing, Marketing Operations, Market Access and Patients Services.

- **Commercialization lead,** creating the brand strategy, go-to-market plan, creative campaign, positioning and messaging to support first-in-class HIF inhibitor, Vadadustat, for CKD Anemia in Dialysis and Non-Dialysis (On hold due to a CRL in March 2022).
  - Led brand and portfolio strategy, AURYXIA commercial strategy, VAFSEO launch readiness and governance, marketing, and commercial operations.
- **Executed pre-market Vadadustat Market Access launch plan** and strategic engagements with key customers inclusive of payers and dialysis providers for pre-label information exchanges to ensure access at product launch.
- **Managed customer engagement strategy** for organized customers (dialysis providers), payer formulary and rebate agreements, and distribution agreements to optimize access and minimize gross to net impact for current in-line asset.

VICE PRESIDENT, MARKET ACCESS AND PATIENT SERVICES ('19 – '21)

Led integrated Market Access function post-Keryx merger. Led strategic account management for large and medium-sized dialysis providers.

- **Executed key AURYXIA contract with largest Renal-focused specialty pharmacy** announced during Q3'19 earnings calls and renewed in Q4'20 for 2021.
- **Successfully negotiated rebate concessions** with Part D plans after CMS imposed an indication-based prior authorization, yielding gross to net savings of approximately $15M in 2020 rebate invoicing.
- **Managed the transition to new access service HUB provider** to improve end-to-end patient and provider support.
- **Developed Regional Specialty Pharmacy Network** for in-line and pipeline renal products inclusive of CKD and dialysis clinical support.
- **Responsible for comprehensive trade function including** distribution (3PL, wholesalers and pharmacies), support services, and reimbursement strategy for in-line and pipeline assets.

SENIOR DIRECTOR, MARKET ACCESS ('18)

Led Market Access build to support Vadadustat launch (commercial and developed partnership with Otsuka). Led pre-commercial market access planning for U.S. and EU including dialysis and payer engagement strategy, value prop development, HEOR development to support.

- **Completed pricing and contracting strategy for both indications of Vadadustat** inclusive of policy determined TDAPA economics for the U.S. dialysis market and established value demonstration for U.S. and EU markets.
- Assessed Market Access build for benchmarking team size to support Vadadustat and integrated functions from Akebia/Keryx merger.
- Supported alliance commercial and market access planning with Otuska for EU and U.S. and Vifor Pharma for Dialysis Market.

REGENERON HEALTHCARE SOLUTIONS, TARRYTOWN, NY 2016 – 2018

SENIOR DIRECTOR, U.S. AND GLOBAL MARKET ACCESS

Developed price, contracting, channel, health economic, and trade strategy for PRALUENT® brand and pipeline assets.

- **Reimagined PRALUENT® commercial strategy gaining alignment with CEO** leveraging Specialty Pharmacy and HUB Analytics, improving access for high-risk CV patients based on reestablished payer Prior Authorization criteria.
  - Achieved Market Access Goals with over 90% covered lives and #1 covered product by entering into innovative contracts with pharmacies and hospitals to unlock access and dramatically increase approvals.
  - Improved Commercial and Medicare approval rates from 20% to ~75%.
  - Improved "approvable patient" lives in two largest PBMs and two national health plans.
- **Developed Global Cardiovascular Outcomes Trial plan** to improve pricing and reimbursement in the EU5 and US pre- and post-CVOT results including development of innovative/value-based contracting.
- **Managed an alliance relationship interfacing** with both global market access affiliates, U.S. and global commercial teams, and leading an internal market access team.

NOVO NORDISK, PRINCETON, NJ 2011 – 2016

BRAND DIRECTOR, MARKET ACCESS, VICTOZA® ('13 – '16)

ASSOCIATE DIRECTOR, MARKET ACCESS ('11 – '13)

- **Achieved double-blockbuster success for Victoza® launch** in the U.S. without cannibalizing diabetes franchise.
- **Extended commercial strategy** from PBM contracts to include educating large, Fortune 500 employers with 400K+ employees on the benefits of making this available to their work force.

Prior Experience:

DRAFT FCB HealthCare, New York, NY – Account Group Supervisor. Managed launch strategy, tactics and $4M launch budget for a specialty injectable biologic product for Novartis. (2011)

FOREST LABORATORIES, New York, NY

- **Segment Marketing Manager** (2009 – 2011)
- **Divisional Sales Manager** (2007 – 2009)
- **Regional Sales Trainer** (2006 – 2007)
- **Hospital Account Executive** (2004 – 2006)
- **Sales Representative / Field Trainer** (2002 – 2004

Leadership & Advisory

Cure MLD Foundation, Strategic Partner (2023 – Present)
MLD Foundation, Strategic Partner (2023 – Present)
Global Genes, Strategic Partner (2024 – Present)
n-lorem Foundation, Subject Matter Expert (2024 – Present)

Education

MBA, Emphasis in Marketing & Finance, University of Washington, Seattle, WA
BA, Biology / Minor in Business, College of Idaho, Caldwell, ID (*Cum Laude*)

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6/8/2026
Date

I, Bennett Smith, **certify that as the designated representative for**

Mandos, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Bennett Smith

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/26/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bennett Smith

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/8/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Massachusetts, ss. County of Suffolk

I, Bennett Smith, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/8/2026

Date

Subscribed and Sworn to before me this 8 day of June, 2026.

Notary Public Signature

JEREMY D. DUBON
Notary Public
Commonwealth of Massachusetts
My Commission Expires July 02, 2032

(Seal)

Mandos LLC® By Beren Therapeutics, a Public Benefit Corporation

Employee List

Peter Cicala
Bennett Smith

4Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH N/A	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10) ■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10)

Section 1: General Information

Facility Name: Tailstorm Health INC DBA Medivant Healthcare

Physical Address: 158 S Kyrene rd

City: Chandler State: AZ Zip: 85226

Mailing Address (if different from physical address): N/A

City: _____ State: _____ Zip: _____

Telephone: 480605520 Website: medivanthealth.com

Name of Designated Representative (DR): Sidra Pervez

Licensing Company Email: licensing@medivanthealth.com DR Email: licensing@medivanthealth.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies ■ Practitioners ■ Hospitals ☐ Wholesalers ☐ Veterinarians ■ Others: clinics	■ Dangerous Drugs ■ Controlled Substances ☐ [a]Medical Products (medical devices, equipment, supplies, gases) ☐ Others:	■ Manufacturer ■ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ☐ Others:

Section 2: ONLY COMPLETE THIS SECTION IF THE COMPANY IS WHOLESALING [a]Medical Products (medical devices, equipment, supplies and gases). Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 3 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Aug 13, 2026
Date

Section 4: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 5: Publicly Traded Corporation

State of Incorporation: N/A`

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): _____

Corporation/Organization Name: Tailstorm Health INC

Mailing Address: 158 S Kyrene rd

City: Chandler State: AZ Zip: 85226

Telephone: 4806055200 Email: licensing@medivanthealth.com

Contact Person Name: Maria Narvaez

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Talsiam Health INC DBA Medivant Healthcare

Facility Name

Mitesh Gandhi

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

Aug 13, 2026

Date

Board Use Only	Date Received: 8/25/26	Amount:

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drug Establishments Current Registration Site

New Search (index.cfm)

Search Results for **Medivant Healthcare**

CSVExcel

Filter: 158

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
TAILSTORM HEALTH INC DBA MEDIVANT HEALTHCARE	3015929581	167439715	API MANUFACTURE; MANUFACTURE; REPACK;	158 S. KYRENE ROAD, CHANDLER, Arizona (AZ) 85226, United States (USA)	12/31/2026

Showing 1 to 1 of 1 entries (filtered from 2 total entries)
Previous1Next
Data Current through: Tuesday, Aug 25, 2026

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

TailStorm Health Inc. DBA Medivant Healthcare - Corporate Officers			
Address:	**158 S Kyrene Rd Chandler AZ 85226**		
Main Number:	480.605.5200		
List/Name of Officers	Position/Title	DOB	ADDRESS
Ramesh Vijayaraghavan	President	[redacted]	
Mitesh Gandhi	Secretary/Director of Operations		
Anuj Patodia	CFO		

OWNER	Ownership%
Janshi Marketing DMCC	23.60%
Janshi Marketing DMCC	10.40%
Jaishiv Investment LLC-FZ	19.31%
Jaishiv Investment LLC-FZ	8.51%
BR Homes LLC	2.75%
CCM & SDM Venture Funding LLC	1.05%
Paul Hench Lemaistre	0.86%
Maya 9793 LLC	0.72%
Siddhanth Investments Limited Partnership	0.72%
Dan Thiessen	0.67%
Jeff Thiessen	0.67%
Jordan Thiessen	0.67%
Chad Parson	0.62%
Sammark LLC	0.62%
Sushma Chamaria	0.52%
Rana Prasad	0.43%
Floki LLC	0.38%
Parijat Chandra	0.38%
Garett Bjorkman	0.33%
Alex Mirbod	0.24%
Joseph Lear	0.24%
Markesh Manocha	0.24%
Ravindra Edupuganti	0.24%
Rohit & Shipla Nichani	0.24%
Sumeet Mittal	0.24%
Jeffrey Grant	0.14%
Kevin Haddad Boise	0.14%
Kris Sammadar	0.14%
Lindsey McGrath	0.14%
Robin Sammadar	0.14%
Shawn K. Kesterson	0.14%
Timothy S. Callan	0.14%
Armor Trust	0.12%
Alpa Gandhi	0.62%
Brandon Bunger	0.36%
Kavyah Ruddha LLC	0.29%
Vantage IRA	0.15%
James Laporta	0.29%
Brass Holdings LLC	0.15%
Cubazoa LP	0.15%
Pandita Enterprises LLC	0.36%

Wilde Family Trust	0.36%
TGPG 2020 Trust	0.07%
JMDRS Inc	0.17%
Shah Investments LLC	0.17%
James T Leathem	0.12%
Gregory J Wong	0.17%
Atanu Sarkar	1.45%
Shipra Diwan	0.36%
1315 Capital Emerging Growth and Buyout, LP	12.94%
1315 Capital Emerging Growth and Buyout Parall	6.08%
Total	100%

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "TAILSTORM HEALTH, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SIXTH DAY OF MARCH, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "TAILSTORM HEALTH, INC." WAS INCORPORATED ON THE TWELFTH DAY OF JANUARY, A.D. 2015.



C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5672894 8300

SR# 20260909994

Authentication: 203237498

Date: 03-06-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

STATE OF ARIZONA

Office of the
CORPORATION COMMISSION

CERTIFICATE OF GOOD STANDING

I, the undersigned Executive Director of the Arizona Corporation Commission, do hereby certify that:

TAILSTORM HEALTH, INC.

ACC file number: F22669267

a foreign corporation, was authorized to transact business or conduct affairs in the State of Arizona on 06/29/2018;

That all annual reports owed to date by said corporation have been filed or delivered for filing, and all annual filing fees owed to date have been paid; and

That, according to the records of the Arizona Corporation Commission, said corporation is in good standing in the State of Arizona as of the date this Certificate is issued.

This Certificate relates only to the legal existence of the above named entity as of the date this Certificate is issued, and is not an endorsement, recommendation, or approval of the entity's condition, business activities, affairs, or practices.

IN WITNESS WHEREOF, I have hereunto set my hand, affixed the official seal of the Arizona Corporation Commission, and issued this Certificate on this date: **10/13/2021**

Matthew Neubert, Executive Director

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 10/03/2025
Receipt Number: 2025209351
Receipt Amount $: 1000.00

Manufacturer - 503B Outsourcer

503B,Compounding – Non-Sterile,Compounding – Sterile

PERMIT NO	EXPIRES
M001454	10/31/2027

Issued to : TAILSTORM HEALTH INC / dba Medivant Healthcare
TAILSTORM HEALTH INC
158 S KYRENE ROAD
CHANDLER, AZ 85226

TAILSTORM HEALTH INC / dba Medivant Healthcare
158 S KYRENE ROAD
CHANDLER, AZ 85226

EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : TAILSTORM HEALTH INC
LICENSE NUMBER : M001454
EXPIRES : 10/31/2027

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	11-30-2026	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, L1	MANUFACTURER	10-17-2025

TAILSTORM HEALTH, INC
DBA MEDIVANT HEALTHCARE
158 S KYRENE RD
CHANDLER, AZ 85226

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	11-30-2026	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, L1	MANUFACTURER	10-17-2025

TAILSTORM HEALTH, INC
DBA MEDIVANT HEALTHCARE
158 S KYRENE RD
CHANDLER, AZ 85226

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. PB12409400502

Application/License No. _____

TAILSTORM HEALTH INC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 158 S KYRENE RD CHANDLER, AZ 85226 (Address of Applicant/Principal), as PRINCIPAL, and PHILADELPHIA INDEMNITY INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of PENNSYLVANIA (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is ONE BALA PLAZA SUITE 100 BALA CYNWYD, PA 19004-0950 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on AUGUST 17, 2026 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 20TH day of AUGUST, 2026.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

ERIC FAUERBACH, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness JASON O'LEARY

Witness TAYLOR M BRANUM

Countersigned by:

Not Needed
Nevada Resident Agent

Posted February 20, 2020

Bond # PB12409400502

PHILADELPHIA INDEMNITY INSURANCE COMPANY
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004-0950

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS: That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint **Eric Fauerbach of Surety Bonds Direct, LLC** its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed **$50,000,000.**

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY on the 14th of November 2016.

RESOLVED: That the Board of Directors hereby authorizes the President or any Vice President of the Company: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto; and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given. And, be it

FURTHER RESOLVED: That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEALTO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 5TH DAY OF OCTOBER 2024.

(Seal)

John Glomb, President & CEO
Philadelphia Indemnity Insurance Company

On this 5th day of October, 2024 before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**; that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed.

Notary Public: Vanessa McKenzie

Commonwealth of Pennsylvania - Notary Seal
Vanessa Mckenzie, Notary Public
Delaware County
My commission expires November 3, 2028
Commission number 1366394
Member, Pennsylvania Association of Notaries

residing at: Linwood, PA

My commission expires: November 3, 2028

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do hereby certify that the foregoing resolution of the Board of Directors and the Power of Attorney issued pursuant thereto on the 5th day October 2024 are true and correct and are still in full force and effect. I do further certify that John Glomb, who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY.

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this 20th day of August, 2024.

Edward Sayago, Corporate Secretary
PHILADELPHIA INDEMNITY INSURANCE COMPANY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Tailstorm Health INC DBA Medivant Healthcare

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 158 S Kyrene rd

City: Chandler State: AZ Zip: 85226

Mailing Address (if different from physical address): N/A

City: State: Zip:

Telephone: 4806055200 Website: medivanthealth.com

Licensing Company Email: medivanthealth.com

Section 2: Personal Information

First: Sidra Middle: Last: Pervez

Alias(es, nicknames, name changes, etc.):

Date of Birt[redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address: 158 S Kyrene rd

City: Chandler State: AZ Zip: 85226

Telephone: 4806055200 Email: licensing@medivanthealth.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Baqai Medical University			03/2014 - 10/2019
Address	**City**	**State**	**Zip**
51, Deh Tor, Gadap Road	Karachi, Pakistan		
Diploma/Degree obtained, if any			
pharmaD			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)		City	State	Zip
2022 - current	[redacted]	Maricopa	AZ	[redacted]
2021-2022		Phoenix	AZ	
2017-2021		Wixom	MI	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Medivant Healthcare			11-2024	
Business Address		**City**	**State**	**Zip**
158 S Kyrene rd		Chandler	AZ	85226
Phone	**Title**		**Number of Employed Hours**	
4806055200	Pharmacist		3,720 hours	

Description of Duties
Oversaw sterile compounding and repackaging operations, verified batch records and production documentation, ensured compliance with FDA cGMP and 503B requirements, supervised pharmacy personnel, reviewed and released compounded and repackaged products, maintained quality and regulatory compliance, managed controlled substances

Business Name			From - To (MM/YY – MM/YY)	
Exceptional Community hospital			03/2024 - 10/2024	
Business Address		**City**	**State**	**Zip**
19060 N John Wayne Pkwy		Maricopa	AZ	85139
Phone	**Title**		**Number of Employed Hours**	
	IPharmacist		1,400 hours	

Description of Duties
Verified and dispensed medications, reviewed medication orders for accuracy and appropriateness, provided clinical consultation to physicians and nursing staff, monitored medication therapy, ensured compliance with state and federal regulations, managed controlled substances, supervised pharmacy staff, maintained medication inventory, and

Business Name			From - To (MM/YY – MM/YY)	
Frys's food and drug			02/2023 - 03/2024	
Business Address		**City**	**State**	**Zip**
20797 N John Wayne Pkwy, Maricopa, AZ 85139		Maricopa	AZ	85139
Phone	**Title**		**Number of Employed Hours**	
	Pharmacist Intern		2,280 hours	

Description of Duties
Assisted pharmacists in dispensing medications, processed prescriptions, prepared and labeled medications, managed inventory, processed insurance claims, provided customer service, and maintained compliance with pharmacy regulations under pharmacist supervision

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Sidra Perez
Original Signature (electronic, copies or stamps not accepted)

Aug 17, 2026
Date

I, Sidra Pervez, **certify that as the designated representative for**

Medivant Healthcare,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SP I am at least 21 years of age;
3. SP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sidra Pervez
Print Name (First, Last)

Sidra Pervez
Original Signature (electronic, copies or stamps not accepted)

Aug 17, 2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sidra Perez
Print Name (First, Last)

Sidra Perez — Aug 17, 2026
Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Sidra Perez, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Sidra Perez — Aug 17, 2026
Original Signature — **Date**

Subscribed and Sworn to before me this 17 day of Aug 2026.

Notary Public Signature

MARIA FERNANDA NARVAEZ
Notary Public - Arizona
Maricopa County
Commission # 639968
My Comm. Expires Dec 19, 2026

(Seal)

Job	Employee Legal Name
.DE - Assistant Director of Engineerin	Patel, Darshakkumar K
CLC - Cleanroom Cleaner	Esparza, Angie B
QAA - QA Associate	Bodige, Sai Divya
SSE - Sales Support Executive	Castillo Soto, Mia Teresita
QAA - Sr. Quality Assurance Associa	Bruyere, Barbara A
CQA - Associate Director-CQA	Patel, Nirmal Ajitbhai Ajitbhai
VPOA - Vice President of Quality	Sharma, Sushil
MDA - MFG Documentation Associate	Srishti Gowri Somashekhar, FNU
CLC - Cleanroom Cleaner	Moreno cano, Santiago
- MGR QA-Manager of Quality Assu	Ellis, Robert Charles
ANA - Analytical Chemist	PETERSON, JASON
ANA - Analytical Chemist	Aguilar, Jazmin
ıgineering & Facility Maintenance Te	Neri, Abraham David
PHAMTEC - Pharmacy Technician	Iodin, zain uddin
MCB - Microbiologist	Johnston, Lennor Edengrace
DIT - Director of IT	Kavishwar, Nandan G
T - Cleanroom Manufacturing Technic	Robles, Hector F
WAREHOU - Warehouse Associate	Reyes Aguirre, Angel A
AA - Administrative Assistant	Latusek, Kayla
VISINP - Visual Inspector	Cedillo, Cristina G
VITMLD - VI Team Lead	Barraza, Odesa A
PEB - VP of Engineering & B2B Sale	Dave, Rashesh Amit
PSP - Pharmaceutical Sales Rep	Zavala, Thalia
EEA - Engineering Associate	Shiki, Carlos Natale
MAS - Marketing Associate	PATEL, AAYUSHI KIRITBHAI
QA - Associate Director of Quality As	Patel, Rajeshkumar G
MANUTEC - Manufacturing Technicia	Rojas, Jorge J
MANUTEC - Manufacturing Technicia	Lopez, Ernesto
QAA - QA Associate	Ganavdiya, Mayank
HRAA - HR Assistant/Recruiter	Sharma, Bhawana
IRHRR - Director of HR and Recruitin	Cardenas, Jose
PHAMTEC - Pharmacy Technician	Westbrook, Quincy Tyler
QAA - QA Associate	Preeti, Fnu
AA - Administrative Assistant	Kientz, Jessica
CPM - Call Center Partnership Manag	Dault, Brian Joseph
MAA - Manufacturing Associate	Gaikwad, Omkar R
MAA - Manufacturing Associate	Khare, Rohan Makarand
VQA - Validation & QMS Associate	Rana, Dhruvkumar Shaileshkumar
AAS - Sales Associate	Bowley, John
MTTLD - Manufacturing Tech Team L	Gonzalez, Edgar O
OFFADM - Office Admin	Urrea Olmos, Silvia Kenia
CEOCEO - CEO-CEO	Gandhi, Viraj
VITMLD - VI Team Lead	Kludy, Steven C
- Assistant Director of Quality Assur	Gutta, Leela Jagadeesh
VISINP - Visual Inspector	Avila Orozco, Maria Carolina
BOK - Bookkeeper	Bijral, Sahiba
SUP - MANSUP-Manufacturing Supe	Chintalapati, Rakesh Varma
Medical Director -Women's Hormone	Norman, Angelina
PHAMTEC - Pharmacy Technician	Castillo Moreno, Yanies E
- Sr. Associate - Quality Assurance	Patil, Yogita Dinanath
AA - Administrative Assistant	Pearson, Ashley

TSR - Territory Sales Representative	Hassett, Hilda Margaret
SIA - Sr. Analyst	Bhatia, Rajat
ACS - Analytical Chemist Supervisor	Kolluri, Yamini
PRS - PRESIDEN-President	Vijayaraghavan, Ramesh
VPG - VP of Global Quality	Ramachandran, Prakash K
IAA - Quality Assurance Associate - I	Varela Rodriguez, Sofia I
MCB - Microbiologist	Talluri, Nithej
EVP - Executive Vice President	Gandhi, Mitesh M
SMM - Senior Manufacturing Manage	ANISHETTY, RANJITH KUMAR
MANMAN - Manufacturing Manager	May, Christianne Nicole
DAN - Data Analyst	Garg, Medhansh
ıgineering & Facility Maintenance Te	Patil, Swapnil Tanaji
PICPIC - PIC	Gaffin, Richard A
CLC - Cleanroom Cleaner	Delgado, Ernesto Patricio
DIREN - Associate Director of Engine	Suthar, Muktesh Kumar B
DIR - Director of Engineering	Pandya, Ankit
LOGENG - Logistics Engineer	Shah, Devansh Ashishkumar
PHARMAC - Pharmacist	Riffer, Jordan
ADD - Associate Director of Qc	Rodrigues, Austin C
QAS - QA Associate	Narvaez, Maria
MW - Assistant Manager of Warehou	JANI, MARGESH RAJENDRAKUMAR
EXECAS - Executive Assistant	Hogan, Kara Marie
SALREP - Sales Representative	Cardenas, Esthela M
MCB - Microbiologist	Rana, Smit Harishbhai
DAN - Data Analyst	Maddineni, Avinash Chowdhary
EEA - Engineering Associate	Menon, Siddharth
QAA - QA Associate	Bodapati, Ravi Taja.
CMOO - CMO	Patodia, Anuj
VBT - VP of Business Technology	Daga, Anand
AAS - Sales Associate	Hernandez-Rico, Edgar
MAA - Manufacturing Associate	Akula, SaiTeja
VISINP - Visual Inspector	Carrillo Rey, Luz Argelia
SDF - Senior Director-Finance	Jikia, Teona
EEA - Engineering Associate	Fino, Ferdinan
CRMP - CRM and AI Platform Analys	Mohammad, Muzaffar Ali
TSR - Territory Sales Representative	Campbell, Amy Suzanne
PHAMTEC - Pharmacy Technician	Savage, Joshua Gordon
DRIVER - Driver	Briceno Carrillo, Isaac B
TSR - Territory Sales Representative	Gibbons, Tristen Michelle
WAREHOU - Warehouse Associate	Salt, Dakota Malcom
SCA - Supply Chain Analyst	Gohel, Harshkumar Maheshkumar
CLN - Cleaner	Alarcon Parada, Nayibe
SCA - Supply Chain Analyst	Patil, Suraj Satish
CRMP - CRM and AI Platform Analys	Talwalkar, Pushkar Suhas
DAN - Data Analyst	Sid, Deesha Deepak
ITENG - IT Engineer	Karanam, Pratyusha Naren
OFC - Office Custodian	Heredia, Alicia
R - Accounts Receivable (AR) Specia	Peoples, Vanessa Christina
MA - Director of Manufacturing and O	Polisetty, Dilip Kumar
MNA - Manufacturing Administrator	Panchal, Sakshiben Sunilkumar
MCB - Microbiologist	Morais, Abraham
WAREHOU - Warehouse Associate	Henley, Anthony J

ADQC - Assistant Director of QC	Gohil, Darshan
QAA - QA Associate	Adimulam, Mallikarjun
QAA - QA Associate	Gore, Shailesh Uttam
QLA - Quality Assurance Associate	Bayalu, Pavani Sai
CLC - Cleanroom Cleaner	Parraga, Jose Leonardo
AA - Administrative Assistant	Levensky, Sherry
QMS - QMS Manager - QA	Rueda, Richard Isaias
ADO - Assistnat Director of Operation	Dahl, Taylor
ADH - Associate Director -HR	Gambrell, L Gabriela
VI2 - Visual Inspector-2	Flores, Ediannys
CSU - Cleaning Supervisor	Valdez, Lorena
FA - Finacial Analyst	Jatakia, Manav P
WAA - Warehouse Admin	Patel, Mitalben V

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	5/14/2025-5/23/2025* FEI NUMBER 3015929581

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mitesh M. Gandhi, VP of Operations and Finance

FIRM NAME	STREET ADDRESS
Tailstorm Health, Inc. dba Medivant Healthcare	158 S Kyrene Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Chandler, AZ 85226-4472	outsourcing facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:
OBSERVATION 1
The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically, your firm's batch records document significant environmental monitoring excursions during filling of sterile drugs.

A) Nonviable particulate counter (NVPC) data for five of six lots we reviewed of the 19 total lots that were manufactured in 2025 using the new ISO 5 RABS filling line indicate numerous action limit results occurred during filling, but your quality unit did not document a thorough investigation. For example, the following five batches were released and the first four listed were distributed:
   - Bupivacaine HCl 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL, lot 2502005, had approximately 73 action limit results for 0.5 micron particles and approximately 104 action limit results for 5 micron particles. The maximum result for 0.5 micron was 39,258 particles/m^3 and the maximum result for 5 micron was 1,237 particles/m^3.
   - Ketamine 1% 10 mg/mL, 5 mL (SDV), lot 2502008, had approximately 1 action limit result for 0.5 micron particles and approximately 3 action limit results for 5 micron particles. The maximum result for 0.5 micron was 31,731 particles/m^3 and the maximum result for 5 micron was 35 particles/m^3.
   - Ketamine 10% 100 mg/mL, 5 mL (MDV), lot 2502009, had approximately eight action limit results for 0.5 micron particles and approximately 14 action limit results for 5 micron particles. The maximum result for 0.5 micron was 11,661 particles/m^3 and the maximum result for 5 micron was 389 particles/m^3.
   - Lidocaine HCl 1%/Epinephrine Bitartrate 10 mcg/mL, 10 mL, lot 2503004, had approximately 17 action limit results for 0.5 micron particles and approximately 160 action limit results for 5 micron particles. The maximum result for 0.5 micron was 47,752 particles/m^3 and the maximum result for 5 micron was 8,021 particles/m^3.
   - Bupivacaine HCl Injection USP 0.25%, 10 mL, lot 2504002, had approximately 21 action limit results for 0.5 micron particles and approximately 38 action limit results for 5 micron particles. The maximum result for 0.5 micron was 154,594 particles/m^3 and the maximum result for 5 micron was 47,526 particles/m^3.

B) Batch records for the first 18 sterile lots manufactured in 2025 using the new ISO 5 RABS filling line document NVPC alert and action limits in the software were set above the limits allowed per ISO guidelines and in the approved procedure SOP.CQC.0068, Environmental Monitoring Program. Your firm discovered this error in about April 2025 but did not conduct a thorough investigation per the Assessment of Non-Viable Particle Count Limit impact assessment approved 05/05/25. We reviewed six of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Nicholas L Hunt, Investigator Ronda R Loyd Jones, Investigator	X Nicholas L Hunt Investigator Signed By: Nicholas L Hunt -S Date Signed: 05-23-2025 11:58:16	5/23/2025

these lots and each experienced multiple excursions beyond the ISO limits for ISO 5 cleanrooms and some had excursions beyond the default limits detailed below. For example, during filling of Bupivacaine HCl 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL, lot 2502005 the 0.5 micron particulate limit was set to 660,002 particles/m3 and a result of 39,258 particles/m3 at the filling station did not trigger an action limit result or initiate an auto-stop on the line so filling continued through this excursion and many others beyond ISO 5 limits.

The default limits used during filling:

- Alert limit for 0.5 micron particles at the Infeed Turn Table was 991 particles/m^3
- Action limit for 0.5 micron particles at the Infeed Turn Table was 15,000 particles/m^3
- Alert limit for 5 micron particles at the Infeed Turn Table was 91 particles/m^3
- Action limit for 5 micron particles at the Infeed Turn Table was 5,000 particles/m^3
- Alert limit for 0.5 micron particles at the Filling Station was 992 particles/m^3
- Action limit for 0.5 micron particles at the Filling Station was 660,002 particles/m^3
- Alert limit for 5 micron particles at the Filling Station was 92 particles/m^3
- Action limit for 5 micron particles at the Filling Station was 255,002 particles/m^3

C) Your approved procedures do not require production technicians or quality personnel take any specific remedial actions, reject vials present on the line during the inspection, or open a quality investigation in response to NVPC action limit results during filling. Examples of batches with no investigation for NVPC action limit excursions include lot 2502001, lot 2502005, lot 2502008, lot 2502009, lot 2503004, and lot 2504002.

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

(This is a repeat observation.)

Specifically, OOS investigations did not always contain complete written justification to support the root cause and conclusions, and investigations were not always expanded to additional lots when implicated by the root cause.

A) Investigations OOS.23.015 (lot 2304001), OOS.24.001 (lot 2312002), and OOS.23.016 (lot 2310001) identified sample handling and preparation at your contract laboratory as the probable root cause for OOS liquid particle count results in finished drug lots but did not include specific actions by analysts that might have caused the OOS. The contract laboratory investigation did not find any laboratory errors. There was no thorough explanation of the discrepancy between your investigation and your contract laboratory's investigation. There was no record of remedial action at your contract laboratory to prevent reoccurrence of the unspecified root cause. Your firm re-tested these lots and then released and distributed them without identifying the source of the particles found in your drug product.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	5/14/2025-5/23/2025* FEI NUMBER 3015929581

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mitesh M. Gandhi, VP of Operations and Finance

FIRM NAME	STREET ADDRESS
Tailstorm Health, Inc. dba Medivant Healthcare	158 S Kyrene Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Chandler, AZ 85226-4472	outsourcing facility

B) Investigations OOS.24.003 (stability lot 2212005, T12_U_CRT), OOS.24.004 (stability lot 2301001, T12_I_CRT), and OOS.23.005 (lots ENG22006 and ENG22007) document multiple bupivacaine assay OOS results for Bupivacaine HCl/Epinephrine Bitartrate injection. Bupivacaine assay was low for one 12-month real-time stability sample, high for one 12-month real-time stability sample, and high for both engineering lots. Your firm determined a weighing or dilution error was the root cause, because the ratio between the standard and sample solution was wider for the OOS lots than passing lots tested at the same time. HPLC system suitability passed, and the laboratory investigation performed by your contract lab did not find any errors. There is no specification or limit for this ratio, and it is not reviewed unless there is a problem with the initial result. Your firm did not expand the investigation to all other lots or even though the root cause identified appears to implicate all assays for this product.

OBSERVATION 3

Acceptance criteria for the sampling and testing conducted by the quality control unit is not adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release.

(This is a repeat observation.)

Specifically, we observed multiple deficiencies when we examined your firm's visual inspection, AQL, and particle identification procedures, processes, and executed records.

A) Your firm did not determine the identity, source, and route of contamination for particles and fibers observed inside sterile finished drug vials during 100% visual inspection and AQL performed post-terminal sterilization for lots we examined. The lots met acceptance criteria for VI and AQL and were released with no additional investigation. For example,

- Inspectors identified 83 units with particles and 16 units with fibers during 100% visual inspection of Sterile Water for Injection, USP 10 mL, lot 2502001.
- Inspectors identified 21 units with particles and eight units with fibers during 100% visual inspection of Bupivacaine HCl 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL, lot 2502005.
- Inspectors identified five units with particles and four units with fibers during 100% visual inspection of Ketamine 1% 10 mg/mL, 5 mL (SDV), lot 2502008. QA found one additional white fiber during AQL.
- Inspectors identified four units with particles and three units with fibers during 100% visual inspection of Ketamine 10% 100 mg/mL, 5 mL (MDV), lot 2502009. QA found one additional white particle during AQL.
- Inspectors identified 2 units with particles and 6 units with fibers during 100% visual inspection of Lidocaine HCl 1%/Epinephrine Bitartrate 10 mcg/mL, 10 mL, lot 2503004. QA found one additional white particle and one additional fiber during AQL.
- Inspectors identified six units with particles and three units with fibers during 100% visual inspection of Bupivacaine HCl Injection USP 0.25%, 10 mL, lot 2504002.

B) QA inspectors compare rejected defect vials from 100% visual inspection that contain particulates and fibers to the defect gallery.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Nicholas L Hunt, Investigator Ronda R Loyd Jones, Investigator X	5/23/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	5/14/2025-5/23/2025* FEI NUMBER 3015929561

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mitesh M. Gandhi, VP of Operations and Finance

FIRM NAME	STREET ADDRESS
Tailstorm Health, Inc. dba Medivant Healthcare	158 S Kyrene Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Chandler, AZ 85226-4472	outsourcing facility

Your current procedures are deficient because they require the QA inspector to visually determine if the particle or fiber is known or unknown and then send the vial for additional identification. There was inadequate explanation how the QA inspector can visually distinguish the composition of similar particles when the description in the defect gallery is a general description such as "black particle". For example, multiple black particles or multiple white fibers will appear similar but might be different materials when examined under microscopy, FTIR, or other identification method. We also noted the procedure applies to defect vials from 100% visual inspection but does not require QA inspectors to compare particles found during AQI. to the defect gallery.

C) There is inadequate written justification to classify particulates and fibers found in terminally sterilized injectable drugs as major defects instead of critical defects. Critical defects have a lower defect limit.

D) You do not have adequate written justification for not identifying all particles and fibers observed during 100% visual inspection and AQL.

OBSERVATION 4
Routine inspection and checking of equipment is not performed according to a written program designed to assure proper performance.

Specifically, we observed the UV lamp unit on your water for injection (WFI) generation skid leaking and creating a puddle on the floor on 05/14/25. There were no records available to determine how long this leak was present. Your firm uses WFI to produce approximately 19 different terminally sterilized injectable drugs. Examples of lots produced with WFI include: Sterile Water for Injection, USP 10 mL, lot 2502001; Bupivacaine HCl 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL, lot 2502005; Ketamine 10% 100 mg/mL, 5 mL (MDV), lot 2502009; and Bupivacaine HCl Injection USP 0.25%, 10 mL, lot 2504002.

OBSERVATION 5
Buildings used in the manufacturing, processing and packing of a drug product are not maintained in a good state of repair.

Specifically, we observed maintenance deficiencies with the cleanrooms production technicians use to manufacture all terminally sterilized injectable drugs including: Sterile Water for Injection, USP 10 mL, lot 2502001; Bupivacaine HCl 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL, lot 2502005; Ketamine 10% 100 mg/mL, 5 mL (MDV), lot 2502009; and Bupivacaine HCl Injection USP 0.25%, 10 mL, lot 2504002.

A) We observed multiple pieces of apparent autoclave tape under the conveyor belt and on the wall surrounding the outlet from the sealing and capping station of the ISO 5 RABS filling line into the ISO 7 autoclave room. There was no written explanation of why the tape was present or how long it was present.

B) We observed a missing electrical outlet cover in the ISO 7 autoclave room with an apparent black substance surrounding the entire outlet. There was no written explanation of how long the outlet cover was missing or the identity of the black substance.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Nicholas L Hunt, Investigator Ronda R Loyd Jones, Investigator	X	5/23/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	5/14/2025-5/23/2025* FEI NUMBER 3015929581

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mitesh M. Gandhi, VP of Operations and Finance

FIRM NAME	STREET ADDRESS
Tailstorm Health, Inc. dba Medivant Healthcare	158 S Kyrene Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Chandler, AZ 85226-4472	outsourcing facility

***DATES OF INSPECTION**
5/14/2025(Wed), 5/15/2025(Thu), 5/16/2025(Fri), 5/19/2025(Mon), 5/20/2025(Tue), 5/21/2025(Wed), 5/22/2025(Thu), 5/23/2025(Fri)

Ronda R. Loyd-jones -S
Digitally signed by Ronda R. Loyd-jones -S
Date: 2025.05.23 15:05:42 -07'00'

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Nicholas L Hunt, Investigator Ronda R Loyd Jones, Investigator	X Nicholas L Hunt Investigator Signed By: Nicholas L. Hunt -S Date Signed: 05-23-2025 14:58:16	DATE ISSUED 5/23/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

TailStorm HEALTH INC. 158 S Kyrene Rd, Chandler, AZ 85226

June 16, 2025

Monica Maxwell, Division Director
Office of Human and Animal Drug Inspectorate (OHADI)
Division of Human and Animal Drug Inspectorate V
Email: Monica.Maxwell@fda.hhs.gov
compoundinginspections@fda.hhs.gov

Subject: Response to FDA's Form "483 Inspectional Observations" issued on May 23, 2025.

Dear Director Maxwell:

Tailstorm Health Inc. dba Medivant Health, a 503B registered outsourcing facility located at 158 S Kyrene Rd, Chandler, AZ 85226, acknowledges receipt of a FDA Form 483 issued at the close of the inspection conducted from May 14, 2025 to May 23, 2025. We thank the investigator for the professional and collaborative manner in which the inspection was conducted.

We take FDA's observations and all associated comments with the utmost seriousness; we value the opportunity this inspection provides to further strengthen our compliance with 21 CFR Parts 210, 211, and Section 503B of the Federal Food, Drug, and Cosmetic Act. Our mission remains centered on providing safe, high-quality compounded drug products to patients, particularly in times of critical drug shortages.

This letter responds to the specific observations noted in the FDA Form 483. Some observations remain under investigation, while others have progressed to the CAPA stage or have been fully addressed and implemented. To support this process, we have engaged third-party consultants, including Jeff Yuen with Jeff Yuen & Associates Inc. and independent consultant Ron Stephens, who are experienced in FDA's current good manufacturing practice regulations (CGMP) and FDA's guidance relevant to outsourcing facilities. Their comprehensive gap assessments and ongoing engagement will help ensure the sustainability and effectiveness of our remediation.

Tailstorm Health is voluntarily pausing compounding operations as of May 23, 2025 so that it may effectively engage in system-wide improvements and the implementation of CAPAs. We will notify the Agency prior to resuming compounding. Tailstorm Health will submit updates to FDA until all remedial actions are completed. We are fully committed to providing necessary resources to support our remediation efforts.

If you have questions about our response or would like to discuss, please contact Sushil Sharma, Head of Quality at s.sharma@medivanthealth.com (phone number 4808756727).

Sincerely,
Mitesh Gandhi,
Vice President-Operations
Tailstorm Health Inc.

TailStorm HEALTH INC. 158 S Kyrene Rd, Chandler, AZ 85226

Executive Statement of Commitment and Voluntary Pause in Compounded Formulations From Affected Production Line (FEI No.: 3015929581)

Tailstom Health Inc. dba Medivant Health acknowledges the observations in the FDA Form 483 and takes both the findings and the investigator's comments seriously. While we believe our Quality Systems are fundamentally robust, we sincerely value the opportunity to improve upon our current Quality System and are committed to continuous improvement, and compliance with FDA's CGMP regulations and the Agency's guidance applicable to Section 503B outsourcing facilities.

As a result of the observations and to demonstrate our commitment to patient safety, we have voluntarily paused compounding operations and initiated a recall of all products within expiry that were produced on our new filling line. Production will not resume on this line until appropriate corrective and preventive actions (CAPAs) are implemented. Tailstorm Health will notify the Agency prior to resuming compounding operations on the affected line.

Since April 28, 2025, we have engaged third-party CGMP experts Jeff Yuen & Associates and Ron Stephens from September 2024 to conduct independent assessments of our Quality Systems and Operations. Their recommendations will guide our remediation plan and system-wide improvements. *Refer Attachment-I for CVs of Engaged Consultant.*

Medivant is fully committed to holistically addressing "gaps" identified at a "quality system or foundational level" vs. simply revising procedures. Detailed CAPA plans will be developed, tracked and trended with target completion dates by Medivant QA with oversight from JYA and Ron Stephens and routine updates shared with FDA as to progress and completion.

Medivant takes pride in supplying critical drug shortage products to customers and patients that rely on them, and remains fully committed to strengthening our Quality Systems to support safe and reliable patient care.

Viraj Gandhi
Chief Executive Officer
Viraj Gandhi

Mitesh Gandhi
Head of Operations
Mitesh Gandhi

Sushil Sharma
Head of Quality
Sushil Sharma

Observation No. 1:

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.
Specifically, your firm's batch records document significant environmental monitoring excursions during filling of sterile drugs.

A. **Nonviable particulate counter (NVPC) data for five of six lots we reviewed of the 19 total lots that were manufactured in 2025 using the new ISO 5 RABS filling line indicate numerous action limit results occurred during filling, but your quality unit did not document a thorough investigation. For example, the following five batches were released and the first four listed were distributed.**

Bupivacaine HCl 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL, lot 2502005, had approximately 73 action limit results for 0.5 micron particles and approximately 104 action limit results for 5 micron particles. The maximum result for 0.5 micron was 39,258 particles/m^3 and the maximum result for 5 micron was 1,237 particles/m^3.

Ketamine 1% 10 mg/mL, 5 mL (SDV), lot 2502008, had approximately 1 action limit result for 0.5 micron particles and approximately 3 action limit results for 5 micron particles. The maximum result for 0.5 micron was 31,731 particles/ m^3 and the maximum result for 5 micron was 35 particles/ m^3.

Ketamine 10% 100 mg/mL, 5 mL (MDV), lot 2502009, had approximately eight action limit results for 0.5 micron particles and approximately 14 action limit results for 5 micron particles. The maximum result for 0.5 micron was 11,661 particles/m^3 and the maximum result for 5 micron was 389 particles/ m^3.

Lidocaine HCl 1%/Epinephrine Bitartrate 10 mcg/mL, 10 mL, lot 2503004, had approximately 17 action limit results for 0.5 micron particles and approximately 160 action limit results for 5 micron particles. The maximum result for 0.5 micron was 47,752 particles/m^3 and the maximum result for 5 micron was 8,021 particles/ m^3.

Bupivacaine HCl Injection USP 0.25%, 10 mL, lot 2504002, had approximately 21 action limit results for 0.5 micron particles and approximately 38 action limit results for 5 micron particles. The maximum result for 0.5 micron was 154,594 particles/ m^3 and the maximum result for 5 micron was 47,526 particles/ m^3.

B. Batch records for the first 18 sterile lots manufactured in 2025 using the new ISO 5 RABS filling line document NVPC alert and action limits in the software were set above the limits allowed per ISO guidelines and in the approved procedure SOP.CQC.0068, Environmental Monitoring Program. Your firm discovered this error in about April 2025 but did not conduct a thorough investigation per the Assessment of Non-Viable Particle Count Limit impact assessment approved 05/05/25. We reviewed six of these lots and each experienced multiple excursions beyond the ISO limits for ISO 5 cleanrooms and some had excursions beyond the default limits detailed below. For example, during filling of Bupivacaine HCl 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL, lot 2502005 the 0.5 micron particulate limit was set to 660,002 particles/m^3 and a result of 39,258 particles/m^3 at the filling station did not trigger an action limit result or initiate an auto-stop on the line so filling continued through this excursion and many others beyond ISO 5 limits.

The default limits used during filling:

- **Alert limit for 0.5 micron particles at the Infeed Turn Table was 991 particles/m^3**
- **Action limit for 0.5 micron particles at the Infeed Turn Table was 15,000 particles/m^3**
- **Alert limit for 5 micron particles at the Infeed Turn Table was 91 particles/m^3**
- **Action limit for 5 micron particles at the Infeed Turn Table was 5,000 particles/m^3**
- **Alert limit for 0.5 micron particles at the Filling Station was 992 particles/m^3**
- **Action limit for 0.5 micron particles at the Filling Station was 660,002 particles/m^3**
- **Alert limit for 5 micron particles at the Filling Station was 92 particles/m^3**
- **Action limit for 5 micron particles at the Filling Station was 255,002 particles/m^3**

C. Your approved procedures do not require production technicians or quality personnel take any specific remedial actions, reject vials present on the line during the inspection, or open a quality investigation in response to NVPC action limit results during filling. Examples of batches with no investigation for NVPC action limit excursions include lot 2502001, lot 2502005, lot 2502008, lot 2502009, lot 2503004, and lot 2504002.

Tailstorm Health's Response:

Tailstorm Health both acknowledges, and recognizes the gravity of, this Observation. We also acknowledge that critical oversights occurred within our functions concerning the new ISO 5 RABS (Restricted Access Barrier System) filling line identified in the Observation. The misconfiguration of non-viable particulate count (NVPC) alert and action limits, the lack of appropriate system checks, and the inadequate review processes represent a lapse in our control systems for the introduction and use of this new equipment.

The responses to Observation 1A, 1B and 1C are addressed in a holistic manner covering the root casue of the findings, impact assessment and corrective actions to prevent the recurrence of the issues.

As a responsible outsourcing facility committed to ensuring product quality and patient safety, Tailstorm Health has voluntarily recalled all distributed batches from the ISO 5 RABS filling line identified in the Observation and quarantined available inventory for destruction. *Refer Attachment 1-1-Recall Communication and Related Documentation.* We have also ceased production on the new filling line. Deviation DEV-2025-0004 has been initiated and a specific root cause determination is in-progress. A protocol based (Protocol no. PROT.GSP.0001) study is ongoing to determine the source of particles which caused the NVPC excursions.

No further manufacturing will occur using this new RABS equipment line until the deviation has been fully investigated, all corrective actions have been fully implemented, requalification of equipment is completed, and our revised procedures have been independently verified and approved by Quality Assurance and our GMP consultants. Tailstorm Health will notify FDA prior to resuming production on this line.

A. Background and Equipment Qualification Overview:

In January 2025, a new automated vial filling and sealing machine (Make: NKP) was installed at our sterile injectable manufacturing facility. This installation was part of a broader initiative to improve production efficiency and control through advanced automation and integrated monitoring systems. Prior to commencing routine production, a protocol-based qualification of the equipment and associated classified areas was undertaken. The equipment qualification included the following phases:

- **Installation Qualification (IQ)**: Confirmed that the equipment was received in good condition, installed according to manufacturer specifications, and utilities were appropriately connected and calibrated. All relevant design specifications, component verifications, and documentation were reviewed and approved.

- **Operational Qualification (OQ)**: Tested the equipment's operational parameters under simulated working conditions. Specific emphasis was placed on verifying safety interlocks, alarms, human-machine interface functionality, machine operations.

- **Performance Qualification (PQ)**: Conducted three consecutive production simulation runs of 5,000 vials for each vial size. Each PQ run involved detailed assessments of the following:
    - Fill volume accuracy through online statistical weight mehod and manual weighin method.
    - Machine throughput and cycle time efficiency.
    - Stopper and seal integrity verification.
    - Automated rejection system functionality based on fill weight, stopper misplacement, and physical defects.
    - In-process checks such as container closure integrity testing (CCIT), visual defect classification, and weight uniformity.
    - AQL-based sampling and visual inspection.

In parallel, the cleanroom areas including the new ISO 5 RABS (Restricted Access Barrier System) of filling machine and adjacent ISO 7 environments were qualified. Key validation activities included:

- **HEPA Filter Integrity Testing (Leak Test)**: Verified using aerosol photometry. All filters demonstrated no detectable leak.
- **Air Velocity Measurements**: Verified to be within acceptable range (90 fpm ±20%) ensuring unidirectional airflow maintenance.
- **Airflow Visualization Study (Smoke Study)**: Conducted under static and dynamic conditions to validate laminar airflow patterns, absence of turbulence, and proper sweeping of critical surfaces.
- **Environmental Monitoring (EM) Qualification**: Conducted over six days (three static, three dynamic) using viable and non-viable particulate monitoring using a calibrated portable NVPC counter.
- **Temp, RH and Differential Pressure Monitoring**: Found within qualified ranges.
- **Area Recovery**: Conducted by exceeding particles 100 times from initial particle count value and observed recovery found within established timeframe.

Inference: All qualification results met the predefined acceptance criteria and were documented in the final qualification report. However, a key procedural gap was identified retrospectively: the NVPC system configuration was not independently verified following vendor setup during qualification. *Refer Attachment 1-2 Performance Qualification Report of Vial Filling and Sealing Machine*

B. Detailed Summary of ISO 5 Environmental Monitoring Qualification Results

Table 1 below includes a detailed summary of all ISO-5 Environmental monitoring data collected during equipment qualification

Table – 1 ISO 5 Qualification Results

Sr. No.	Qualification Parameter	Acceptance Criteria (ISO 5 Area)	Sampling Location	Results					
				Static			Dynamic		
				Day-1	Day-2	Day-3	Day-1	Day-2	Day-3
1.	Viable Count (Settle Plate)	<1 cfu/plate	Near turn Table	0	0	0	0	0	0
2.			Near Filling and Stoppering Station	0	0	0	0	0	0
3.			Near Sealing Station	0	0	0	0	0	0
4.	Viable Count (Active Air Sampler)	<1 cfu/ m^3	Near Turn Table	0	0	0	0	0	0
5.			Near Filling and Sealing	0	0	0	0	0	0
6.	Viable Count (Contact Plate)	<1 cfu/plate	On Turn Table	0	0	0	0	0	0
7.			On Buffer Tank	0	0	0	0	0	0
8.			Stopper Bowl	0	0	0	0	0	0
9.	Non-Viable Particulate Count (≥0.5µm)	< 3520 particles/m^3	Near turn Table	0	0	0	77	0	0
			Near Filling and Stoppering Station	0	0	0	0	0	0
			Near Sealing Station	0	0	0	0	0	0
10.	Non-Viable Particulate Count (≥5µm)	< 29 particles/m^3	Near turn Table	0	0	0	0	0	0
			Near Filling and Stoppering Station	0	0	0	0	0	0
			Near Sealing Station	0	0	0	0	0	0
11.	Air Velocity	72 to 108 fpm	Supply 1	89 FPM					
			Supply 2	92 FPM					
			Supply 3	98 FPM					

Sr. No.	Qualification Parameter	Acceptance Criteria (ISO 5 Area)	Sampling Location	Results					
				Static			Dynamic		
				Day-1	Day-2	Day-3	Day-1	Day-2	Day-3
			Supply 4	99 FPM					
			Supply 5	101 FPM					
			Supply 6	90 FPM					
12.	HEPA Filter Leak Test	<0.001%	Supply 1	0%					
			Supply 2	0%					
			Supply 3	0%					
			Supply 4	0%					
			Supply 5	0%					
			Supply 6	0%					
13.	Airflow Visualization (Smoke Test)	-Unidirectional Flow Patterns -No refluxing. No swirling, pulsing, or bulging of the air stream -No observed backflow from ISO 7 space into RABS	Assembling of Parts	Complies					
			Static condition	Complies					
			Dynamic Condition	Complies					
			Interventions	Complies					
14.	Area Recovery	<5 Minutes	Filling and Stoppering Station	2 Minutes					

All qualification results met the predefined acceptance criteria and were documented in the final qualification report which is attached for review. *Refer Attachment 1-3_Area Qualification Report*

C. Description of Installed NVPC Monitoring System and Alert/Action Limit Configuration

The installed NKP automatic vial filling machine is equipped with an integrated, automated, real time non-viable particle counting (NVPC) system. This system includes high-precision particle counters installed at two locations:

- Infeed Turn Table
- Filling and Stoppering Station

This system is designed to detect airborne particulate contamination in real-time, log the data, and trigger alarms or automated shutdowns in case alert or action limits are breached. The integration

of NVPC with the filling system ensures early detection of contamination risks during critical filling operations.

During Operational Qualification (OQ), the alarm functionalities were successfully challenged using simulated excursions by manipulating analog input signals (4–20 mA) to mimic high particle count values. These simulations were performed to verify the integrated NVPC system along with the alarm and interlock response to stop the machine.

The PQ protocol focused on equipment functionality and did not include evaluation of the integrated NVPC limits and reports. All PQ acceptance parameters were met. The NVPC misconfiguration was not detected or verified during the Performance Qualification of the new vial filling and sealing machine by the equipment manufacturer or Tailstorm. The root cause of the misconfiguration will be covered in deviation, DEV-2025-0004.

However, it was later discovered before manufacturing Lot No. 2504004 that the configured alert and action limits were erroneously high, resulting in no alarms being generated during actual environmental excursions.

This oversight led to multiple undetected excursions in NVPC readings during the manufacturing of 18 commercial lots.

Due to the limits being set significantly above ISO 5 thresholds (e.g., 660,002 particles/m^3 for 0.5µm instead of 3,520), these safety features were rendered ineffective.

D. Detailed Summary of NVPC Excursions and Affected Batches

Following the commissioning of the new NKP filling line, a total of 19 commercial lots were manufactured between February and April 2025. Environmental monitoring data captured during these production runs revealed excursions in non-viable particle counts (NVPC), at the 0.5µm and 5µm particle size ranges. Upon retrospective review, it was found that numerous batches had exceeded ISO 5 action limits without triggering system alarms due to misconfigured alert and action thresholds.

Before manufacring 19th lot, the lmits of NVP counts were corrected as per ISO5 requirements.

The following table-2 summarizes the observed NVPC values and excursions of all 19 lots:

Table-2 Summary of NVPC Excursions for 19 Commercial Lots on NKP Filling Line (Feb–Apr 2025)

Batch Number	Product Name	No. of Excursions (0.5 micron)	No. of Excursions (5 micron)	Max. 0.5 micron (Particles/m^3)	Max. 5 micron (Particles/m^3)
2502001	Sterile Water for Injection, USP 10ml	0	0	177	0
2502002	Sterile Water for Injection, USP 10ml	8	9	26714	1979
2502003	Sodium Chloride 0.9% USP, 10 ml	1	5	27774	106
2502004	Lidocaine 1% USP 10mg/ml, 10ml	11	23	91201	4770
2502005	Bupivacaine Hydrochloride 0.5% Epinephrine Bitartrate 5mcg/ml Inj, 10ml	73	104	39258	1237
2502006	Bupivacaine Hydrochloride 0.5% Epinephrine Bitartrate 5mcg/ml Inj, 10ml	10	46	239682	8834
2502007	Bupivacaine Hydrochloride 0.5% Epinephrine Bitartrate 5mcg/ml Inj, 10ml	15	85	19435	565
2502008	Ketamine 1% 10mg/ml, 5ml (SDV)	1	2	31731	35
2502009	Ketamine 10% 100mg/ml, 5ml (MDV)	8	14	11661	389
2503001	Ketamine 1% 10mg/ml, 5ml (SDV)	18	24	195618	48516
2503002	Ketamine 10% 100mg/ml, 5ml (MDV)	22	37	575053	162580
2503003	Lidocaine 1% USP 10mg/ml, 10ml	4	12	15371	4205
2503004	Lidocaine HCL 1% Epinephrine	12	100	477562	8021

Batch Number	Product Name	No. of Excursions (0.5 micron)	No. of Excursions (5 micron)	Max. 0.5 micron (Particles/m^3)	Max. 5 micron (Particles/m^3)
	Bitartrate 10mcg/ml, 10ml				
2503005	Lidocaine HCL 1% Epinephrine Bitartrate 10mcg/ml, 10ml	310	312	88163	459
2503006	Lidocaine 1% USP 10mg/ml, 10ml	7	11	21307	3074
2504001	Lidocaine HCL 2% Epinephrine Bitartrate 5mcg/ml, 10ml	315	315	88304	1413
2504003	Lidocaine 2% USP 20mg/ml, 10ml	0	6	1201	283
2504002	Bupivacaine HCL Injection USP 0.25%, 10ml	19	31	154594	47526
2504004	Bupivacaine HCL Injection USP 0.5%, 10ml	0	1	671	177

Inference: The table confirms that 18 of the first 19 lots produced in 2025 exceeded ISO 5 NVPC action limits.. Due to misconfigured alert/action thresholds, these excursions went undetected in real-time and were not investigated. These lots are included as part of the recall.

E. Root Cause Investigation and Simulation Studies

Upon identifying the pattern of excessive NVPC results and the absence of corresponding alarms and machine stops, a comprehensive root cause investigation was initiated. This investigation is ongoing and is being executed under a deviation report no. DEV-2025-0004:

- Determine the reason for the incorrect NVPC alert/action set limits
- Identify any contributing mechanical, procedural, or environmental factors leading to the elevated particle counts
- Assess why reviewers failed to identify NVPC excursions prior to batch release
- Assess why an impact assessment was carried out after identification of incorrectly set limits

E1. Configuration Root Cause (Software Error by Vendor)

The root cause of the non-viable particulate count (NVPC) excursion issue was traced to the retention of default software configuration settings during the commissioning of the NKP vial

filling and sealing machine. Specifically, during the development and testing phases of the machine software, the NVPC alert and action limits were populated with placeholder or randomly assigned numerical values by the equipment manufacturer as part of standard factory setup. These placeholder values were not revised, verified, or cross-checked by Tailstorm Health during equipment qualification.

Although alarm and interlock challenges were performed during Operational Qualification (OQ) by simulating particle excursions using analog signal manipulation (4–20 mA), these tests did not verify the actual configured NVPC thresholds.

As a result, the software limits remained set significantly above ISO 5 environmental monitoring standards, rendering the built-in alarm system and automatic line-stoppage functions ineffective during actual excursions.

Additionally, the verification was missed during PQ because the Performance Qualification (PQ) of the ISO5 RABS of vial filling and sealing machine was carried out using portable NVPC counters over three days each under static and dynamic conditions, in conjunction with the area qualification. In contrast, the PQ of the machine focused solely on verifying its functionality and performance without a review or validation of pre-configured NVPC software thresholds or reports.

E2. Failure in Batch Record Review Process

The review process conducted by manufacturing and quality personnel relied on the machine's auto-generated alarm reports as the primary method to assess environmental compliance. This practice had originated from historical use of the DARA filling machine, which was integrated with Lighthouse software - a system that provided clear alarm reports for NVPC excursions. *Refer Attachment 1-4_Alarm Report of NVP Count from Lighthouse for Dara Filling Machine (ISO5)*

However, the new NKP machine featured a different format and structure for logging NVPC data, and no alarm reports were generated due to misconfigured thresholds. As a result, reviewers did not examine the full NVPC trend data. The procedural gap in reviewer training and the lack of standardized review of all EM data contributed to this oversight. *Refer Attachment 1-5_Alarm Report of NKP Filling Machine and Attachment 1-6_Batchwise NVPC Sample Report*

E3. Preparation of Impact Assessment Document and Missed Deviation Initiation:

One of the investigation objectives was to assess why only an impact assessment was carried out after the identification of incorrect NVPC alert/action limits and why no deviation was raised when these errors were first recognized.

Upon review, it was determined that Manufacturing and Quality reviewers were reliant on the machine's auto-generated alarm reports as their primary tool for Environmental Monitoring, in

line with past practices from the DARA system, which clearly indicated any NVPC excursions. In the case of the NKP machine, although the alarm reports were reviewed, no alarms were generated due to the misconfigured thresholds. When the incorrect NVPC alert/action limits were eventually identified by Tailstom, the reviewers assumed that the issue was solely due to configuration errors and did not identify the NVPC excursions in these 18 lots.

Consequently, the review team proceeded directly to prepare an impact assessment document focused on the configuration error itself, without initiating a formal deviation to assess potential product impact or review retrospective environmental data. The lack of alarm notifications and absence of clear procedural guidance on how to handle such discrepancies contributed to this oversight. *Refer Attachment 1-7_Impact Assessment Document*

This gap indicates a lack of awareness and training among Manufacturing and Quality reviewers regarding the criticality of NVPC threshold limits and the requirement to initiate deviations when systemic data monitoring failures are detected. Additionally, the batch record review procedure does not mandate reviewers recording and escalating excursions related to NVPC monitoring.

E4. Simulation Study for Root Cause of Particle Excursions:

To investigate potential physical and environmental causes of the high NVPC counts observed during vial filling operations, a comprehensive hypothesis-driven simulation study was executed under Protocol No.: PROT.GSP.0001 as part of the root cause analysis for deviation DEV-2025-0004. *Refer Attachment 1-8_NVPC Excursion Simulation Study Protocol for Vial Filling and Sealing Machine*

Study Objective: To identify and confirm possible contributors to non-viable particle (NVP) excursions in the ISO 5 zone using structured test conditions with defined controls and acceptance critera.

1. **Cleaning Solution Residue on Sensors**:
    - **Objective of Hypothesis**: To evaluate whether cleaning agents, particularly IPA, sprayed near or onto the isokinetic probe of the NVPC sensor may aerosolize into the sensor inlet and produce false or elevated particle readings during or after filling line cleaning activities.
    - ***Results***: *Brief transient excursion observed (3 minutes), followed by rapid recovery; not representative of actual NVPC trends during production.*
2. **NVPC Sensor Malfunction or Calibration Drift**:
    - **Objective of Hypothesis**: To verify whether the NVPC sensor was functioning accurately and within calibration limits by reviewing calibration records and conducting OEM diagnostic testing to rule out sensor-related anomalies in particle detection.

- **Results**: *Under Investigation*

3. **HEPA Filter Integrity Issues**:
   - **Objective of Hypothesis**: To determine whether leakage or damage in the HEPA filtration system could be a contributing factor to elevated NVPC levels, through aerosol challenge testing using PAO and scanning photometry.
   - ***Results***: *Passed. Aerosol challenge testing confirmed integrity with no leaks observed. Measured air velocities and airflow patterns were within acceptable limits.*
4. **Vial Breakage During Filling**:
   - **Objective of Hypothesis**: To simulate breakage of glass vials under typical machine conditions to evaluate if shattered glass particles and associated cleaning activities result in particulate spikes detectable by NVPC sensors during filling operations.
   - ***Results***: *The simulation demonstrated particle excursions that closely resemble the patterns observed during actual production runs. Based on these findings, vial breakage and associated cleaning activities has been identified as a probable contributor to the NVPC excursions. Tailstorm Health is currently conducting multiple confirmatory runs to validate this hypothesis under controlled and repeatable conditions. Results from these validation runs will be included in the final investigation summary.*
5. **Compressed Air Leaks Near Sensor**:
   - **Objective of Hypothesis**: To assess whether leaks or exhaust bursts from pneumatically operated valves or cylinders generate mechanical disturbances or particles that trigger NVPC excursions near the sensor.
   - ***Results***: *No excursions were observed during simulated exhaust or leak conditions.*
6. **Nitrogen Gas Flow Near NVPC Probe**:
   - **Objective of Hypothesis**: To determine if the high-velocity discharge of nitrogen gas near the NVPC sensor can interfere with accurate particle sampling, either by disturbing airflow or simulating particulate presence.
   - ***Results***: *Under Investigation*
7. **Ingress of Vial Trays without Disinfection**:
   - **Objective of Hypothesis**: To test whether introducing non-sanitized or improperly cleaned vial trays into the ISO 5 environment can elevate particle counts, especially in areas close to the filling zone during dynamic operations.

Results: *No excursions were observed during simulated condition of vial trays without disinfection.*

8. Interventions During Operation:

- **Objective of Hypothesis**: To assess whether specific open-door or closed-door interventions performed during vial filling operations contribute to spikes in non-viable particle counts in the ISO 5 zone.

- ***Results***: *Simulated interventions did not result in excursions matching historical patterns.*

9. Maximum Vibration of Stopper Bowl and Seal Bowl:

- **Objective of Hypothesis**: To evaluate whether operating the stopper and seal bowl at maximum vibration frequency contributes to increased mechanical particle generation, potentially triggering NVPC excursions within the ISO 5 zone.

- ***Results***: *Under Investigation*

10. Environment Isolation Using Inline HEPA Filter on NVPC Sensor

- **Objective of Hypothesis**: To determine whether elevated NVPC levels are caused by ambient contamination from the ISO 5 environment by isolating the sensor inlet using an inline HEPA filter, thereby feeding only clean air into the sensor for control comparison.

- ***Results***: *Under Investigation*

E5. Independent Verification of NVPC Configuration Program:

As an extension of the simulation study and ongoing root cause investigation, Tailstorm Health will implement a formal verification program for the NVPC configuration settings on the NKP vial filling and sealing machine. This verification will be conducted collaboratively by the equipment manufacturer (NKP) and an independent third-party validation expert to ensure that the NVPC alert and action limits are correctly configured. The verification process will include review of source code logic, sensor mapping, threshold values, alarm setpoints, and data reporting mechanisms. All findings and corrective actions will be documented and included as part of the final root cause summary.

Outcome of Root Cause Investigation:

- **Root Cause of Incorrect Set Limits:** The primary root cause for NVPC system failure was improper configuration of alert and action limits by the machine vendor, compounded by lack of post-validation review by Engineering, Manufacutirng and Quality Assurance of Taisltorm.

- **Root Cause of NVPC Excursion:** The specific root cause of the NVPC excursions is currently under investigation as part of the structured root cause analysis initiated under Protocol No.: PROT.GSP.0001, associated with deviation DEV-2025-0004. The investigation includes simulation studies, equipment performance assessments, environmental controls review, and evaluation of potential contributors. *Refer Attachment 1-9 Interim Report of NVPC Excursion Simulation Study for Vial Filling and Sealing Machine*

  Upon completion of the full simulation study and confirmatory evaluation of the probable causes, a comprehensive investigation summary, finalized root cause conclusion, and corrective and preventive action (CAPA) plan will be submitted to the FDA in a follow-up response.

- **Root Cause of Reviewer oversight:** Reviewer oversight occurred due to continued reliance on old review practices, lack of familiarity with the new system's data format, and absence of a structured review SOP for raw NVPC data.

- **Root Cause of Delayed Deviation Initiation:** Upon discovering misconfigured limits, reviewers assumed the issue was limited to configuration only and did not anticipate any real-time excursions due to the absence of alarms. This led to the preparation of an impact assessment without initiating a formal deviation.

F. Impact Assessment

The assessment of potential impact from the NVPC excursions was conducted. This assessment considered the severity of the excursions, the sterility assurance mechanisms in place, and the results of all product release tests.

F1. Environmental Controls and Monitoring Data

Despite the elevated NVPC readings, all viable environmental monitoring (EM) results during the filling operations for the 19 affected lots remained within the acceptable limits defined for ISO 5 environments. This included:

Table – 3 Viable Environmental Monitoring Results During Filling

Batch Number	Product Name	Viable Results (Settle Plates) Action Limit: ≥1 CFU/Plate	
		Near Filling and stoppering station	Near Turn Table
2502001	Sterile Water for Injection, USP 10ml	0 CFU/Plate	0 CFU/Plate
2502002	Sterile Water for Injection, USP 10ml	0 CFU/Plate	0 CFU/Plate

Batch Number	Product Name	Viable Results (Settle Plates) Action Limit: ≥1 CFU/Plate	
		Near Filling and stoppering station	Near Turn Table
2502003	Sodium Chloride 0.9% USP, 10 ml	0 CFU/Plate	0 CFU/Plate
2502004	Lidocaine 1% USP 10mg/ml, 10ml	0 CFU/Plate	0 CFU/Plate
2502005	Bupivacaine Hydrochloride 0.5% Epinephrine Bitartrate 5mcg/ml Inj, 10ml	0 CFU/Plate	0 CFU/Plate
2502006	Bupivacaine Hydrochloride 0.5% Epinephrine Bitartrate 5mcg/ml Inj, 10ml	0 CFU/Plate	0 CFU/Plate
2502007	Bupivacaine Hydrochloride 0.5% Epinephrine Bitartrate 5mcg/ml Inj, 10ml	0 CFU/Plate	0 CFU/Plate
2502008	Ketamine 1% 10mg/ml, 5ml (SDV)	0 CFU/Plate	0 CFU/Plate
2502009	Ketamine 10% 100mg/ml, 5ml (MDV)	0 CFU/Plate	0 CFU/Plate
2503001	Ketamine 1% 10mg/ml, 5ml (SDV)	0 CFU/Plate	0 CFU/Plate
2503002	Ketamine 10% 100mg/ml, 5ml (MDV)	0 CFU/Plate	0 CFU/Plate
2503003	Lidocaine 1% USP 10mg/ml, 10ml	0 CFU/Plate	0 CFU/Plate
2503004	Lidocaine HCL 1% Epinephrine Bitartrate 10mcg/ml, 10ml	0 CFU/Plate	0 CFU/Plate
2503005	Lidocaine HCL 1% Epinephrine Bitartrate 10mcg/ml, 10ml	0 CFU/Plate	0 CFU/Plate
2503006	Lidocaine 1% USP 10mg/ml, 10ml	0 CFU/Plate	0 CFU/Plate
2504001	Lidocaine HCL 2% Epinephrine Bitartrate 5mcg/ml, 10ml	0 CFU/Plate	0 CFU/Plate
2504003	Lidocaine 2% USP 20mg/ml, 10ml	0 CFU/Plate	0 CFU/Plate
2504002	Bupivacaine HCL Injection USP 0.25%, 10ml	0 CFU/Plate	0 CFU/Plate
2504004	Bupivacaine HCL Injection USP 0.5%, 10ml	0 CFU/Plate	0 CFU/Plate

These findings indicate that microbial contamination was not present in the filling area during the production of affected batches, further reducing the risk of product contamination.

In addition to the batch-specific viable monitoring during filling, weekly environmental monitoring data for both viable and non-viable parameters in ISO 5 and ISO 7 areas also indicated no excursions or abnormal trends throughout the production period for these lots. All results for settle plates, contact plates, active air, and NVPC remained within acceptable action and alert limits as per the validated EM program. *Refer Attachment 1-10_Environmental Monitoring Trend of Q-1 and Attachment 1-11_Environmental Monitoring Trend of Q-2 (April & May)*

F2. Terminal Sterilization Efficacy

All products filled on the NKP line underwent terminal sterilization using a validated autoclave cycle at 121°C. The sterilization process validation demonstrated the ability to achieve a Sterility Assurance Level (SAL) of 10^-6. Periodic biological indicator (BI) monitoring and thermocouple mapping of load configurations confirmed uniform lethality across load positions.

Sterilization cycles for each affected lot were reviewed and found to be compliant with:

- Temperature Hold Values
- Sterilization Hold Times
- Chemical Indicator results (Pass)

This step acts as a definitive microbial kill, thereby mitigating any residual risk from airborne particulate co-carrying organisms.

F3. Product Release Testing Results

Every affected batch underwent standard in-process and release testing, including:

- **Sterility Testing (per USP <71>):** No microbial growth detected after 14-day incubation.
- **Bacterial Endotoxin Testing (BET, per USP <85>):** Results within allowable limits (<0.25 EU/mL).
- **Sub-visible Particulate Matter Testing (per USP <788>):** Results complied with both Method 1 (light obscuration) and Method 2 (microscopic count), depending on the product type.

Table – 4 Sterility, Bacterial Endotoxin, and Particulate Matter (LPC) Results for Affected Batches

Batch Number	Product Name	Sterility Test Results (No growth should be detected)	BET Results	LPC Results	
				≥10µm- NMT 6000 particles per vial	≥25µm- NMT 600 particles per vial
2502001	Sterile Water for Injection, USP 10ml	No growth	Limit: <0.25 EU/mL Result: <0.015 EU/mL	81	1
2502002	Sterile Water for Injection, USP 10ml	No growth	Limit: <0.25 EU/mL Result: <0.015 EU/mL	39	2
2502003	Sodium Chloride 0.9% USP, 10 ml	No growth	Limit: <0.5 EU/mg Result: <0.5 EU/mg	35	0
2502004	Lidocaine 1% USP 10mg/ml, 10ml	No growth	Limit: <1.1 EU/mg Result: <0.01 EU/mg	31	1
2502005	Bupivacaine Hydrochloride 0.5% Epinephrine Bitartrate 5mcg/ml Inj, 10ml	No growth	Limit: <1.6 EU/mg Result: <0.01 EU/mg	21	0
2502006	Bupivacaine Hydrochloride 0.5% Epinephrine Bitartrate 5mcg/ml Inj, 10ml	No growth	Limit: <1.6 EU/mg Result: <0.01 EU/mg	21	0
2502007	Bupivacaine Hydrochloride 0.5% Epinephrine Bitartrate 5mcg/ml Inj, 10ml	No growth	Limit: <1.6 EU/mg Result: <0.01 EU/mg	21	0
2502008	Ketamine 1% 10mg/ml, 5ml (SDV)	No growth	Limit: <0.4 EU/mg Result: <0.05 EU/mg	8	1
2502009	Ketamine 10% 100mg/ml, 5ml (MDV)	No growth	Limit: <0.4 EU/mg Result: <0.05 EU/mg	29	1

Batch Number	Product Name	Sterility Test Results (No growth should be detected)	BET Results	LPC Results	
				≥10µm-NMT 6000 particles per vial	≥25µm-NMT 600 particles per vial
2503001	Ketamine 1% 10mg/ml, 5ml (SDV)	No growth	Limit: <0.4 EU/mg Result: <0.05 EU/mg	19	2
2503002	Ketamine 10% 100mg/ml, 5ml (MDV)	No growth	Limit: <0.4 EU/mg Result: <0.05 EU/mg	30	4
2503003	Lidocaine 1% USP 10mg/ml, 10ml	No growth	Limit: <1.1 EU/mg Result: <0.01 EU/mg	3	0
2503004	Lidocaine HCL 1% Epinephrine Bitartrate 10mcg/ml, 10ml	No growth	Limit: <0.7 EU/mg Result: <0.003 EU/mg	20	1
2503005	Lidocaine HCL 1% Epinephrine Bitartrate 10mcg/ml, 10ml	No growth	Limit: <0.7 EU/mg Result: <0.003 EU/mg	17	0
2503006	Lidocaine 1% USP 10mg/ml, 10ml	No growth	Limit: <1.1 EU/mg Result: <0.01 EU/mg	26	1
2504001	Lidocaine HCL 2% Epinephrine Bitartrate 5mcg/ml, 10ml	No growth	Limit: <0.7 EU/mg Result: <0.002 EU/mg	13	0
2504003	Lidocaine 2% USP 20mg/ml, 10ml	No growth	Limit: <1.1 EU/mg Result: <0.01 EU/mg	18	0
2504002	Bupivacaine HCL Injection USP 0.25%, 10ml	No growth	Limit: <2.5 EU/mg Result: <0.024 EU/mg	121	0
2504004	Bupivacaine HCL Injection USP 0.5%, 10ml	No growth	Limit: <2.5 EU/mg Result: <0.012 EU/mg	4	0

These results validate the final products conformity with established quality standards.

F4. Historical Control Comparison

A retrospective review was conducted on NVPC data for previous lots manufactured using the DARA automatic filling line. This included review of alarm reports archived in Lighthouse software for last 24 months. *Refer Attachment 1-12_Historical NVPC Alarm Summary from DARA Automatic Filling Line (Past 24 Months)*

No NVPC excursions during active filling process or review discrepancies were identified during this review. These findings confirm that the NVPC monitoring and review processes were robust until the introduction of the new NKP system.

F5. Product LifeCycle after Commercialization

No adverse events (ADEs) or product complaints were associated with any of the lots manufactured on the new vial filling line.

F6. Conclusion of Impact Assessment

Based on the entirety of data assessed including viable monitoring, terminal sterilization validation, and finished product release testing it is concluded that the product quality was not adversely impacted by the NVPC excursions. Nevertheless, in adherence to a "Quality First" culture and approach, all distributed lots were recalled and quarantined lots were rejected to ensure compliance and maintain regulatory confidence.

However, as the root cause investigation is ongoing, this impact assessment is considered "interim". Upon completion of the simulation and confirmatory studies, the assessment will be completed. Any identified risks will be addressed in the final root cause and CAPA, which will be submitted in a follow-up response.

G. Immediate Action Taken:

1. **Batch Recall and Rejection**:
    - All distributed batches affected by the NVPC monitoring issue (10 total) were voluntarily recalled.
    - Remaining non-distributed batches (9 total) were rejected, quarantined and removed from the warehouse inventory.

H. Corrective and Preventive Actions (CAPA):

Based on the preliminary conclusions of the ongoing root cause investigation, comprehensive Corrective and Preventive Action (CAPA), plan was developed. The current CAPA addresses system configuration issues, enhances process controls, mandates staff retraining, and updates

procedural requirements to prevent recurrence. The CAPA is focused on remediation, system enhancement, staff retraining, and procedural revision to ensure prevention of recurrence.

Upon final confirmation of the root cause, any additional risks or failure modes identified particularly those related to particulate generation and handling will be addressed through expanded CAPA actions. These additional CAPAs will be communicated in the follow-up submission to ensure complete alignment with regulatory expectations.

1. **Requalification of Equipment**:

   - The NKP filling machine will undergo complete requalification including OQ, PQ and Computer System Validation.
   - NVPC system thresholds were corrected to reflect ISO 5 alert and action limits as per ISO 14644-1.
   - Alarm and interlock simulations shall be re-performed under revised settings to verify fail-safe operation.
   - Performance Qualification of NKP filling machine will include consecutive three runs with online monitoring of non-viable particle count with all interventions.

   Target Completion Date: Aug 15, 2025

2. **Review and Rectification of Software Configuration**:

   - All machine configuration files shall be audited by a third party.

   Target Completion Date: July 15, 2025

3. **Reviewer Qualification**:

   - The SOP for Reviewer Qualification will be prepared to define parameters and acceptance criteria to qualify the reviewers.
   - All Manufacturing and Quality Assurance (QA) reviewers will be qualified on reviewing batch record and environmental monitoring data.

   Target Completion Date: July 30, 2025

4. **Batch Record Review SOP Revision (SOP.CQA.0018)**:

   - The SOP for batch record review and batch disposition will be revised.
   - The SOP will required evaluation of both alarm reports and the detailed NVPC report.
   - Review checklists will be updated to include the mandatory documentation of:

     - Review and elevate to Quality Management any excursions during batch record review.

- All validated parameters and observed in-process results.
- Environmental Monitoring (EM) data trends and excursions.
- Good Documentation Practices (GDP) compliance checks.
- Good Manufacturing Practice (GMP) adherence.
- Status of Change Controls, Deviations, and Breakdown Records impacting the batch.

Target Completion Date: July 30, 2025

5. **New SOP for Handling of Excursions in Non-viable Particle Count:**

   - A new Standard Operating Procedure (SOP) will be prepared to define actions to be taken in case of NVPC excursion during filling process.
   - The SOP will clearly define immediate actions during NVPC excursions, criteria for acceptable recovery time, thresholds to resume operations and documentation requirements for excursions, including correlation with environmental and product risk.
   - Interventions shall be recorded in batch manufacturing records (BMR) and cross-referenced with NVPC data to establish correlation and enable traceability.

   Target Completion Date: July 15, 2025

6. **Quarterly Trending of NVPC Data**:

   - A formal trend analysis program will be introduced to detect deviations or recurring patterns in environmental data.
   - Trends will be reviewed during Annual Product Quality Review (APQR) and escalated for investigation when anomalies arise.

   Target Completion Date: Aug 15, 2025

7. **System Verification Program for Critical Equipment**:

   - A comprehensive verification plan will be established for all validated systems, including:
     - **Autoclave**: Verification of cycle parameters (temperature, hold time, vacuum levels).
     - **Compounding Vessels**: Confirmation of CIP/SIP parameters (flow, time, temperature, pressure).
     - **Lighthouse Monitoring Software**: Validation of alert/action limits, report generation, and system integrity.

   Target Completion Date: Aug 15, 2025

8. Change Control Enhancement:

- Change control procedure (SOP.CQA.0054) will be revised to include explicit guidance requiring a structured impact assessment based on the nature and criticality of the proposed change. A new clause will mandate that any modifications to qualified equipment settings particularly those affecting validated or quality critical parameters must be evaluated through formal change control and approved by Quality Assurance prior to implementation. This ensures that changes are not made in isolation or without a full understanding of their regulatory and operational impact.
- To support consistent application of this requirement, an annexure will be introduced in the SOP that outlines predefined categories of changes, their potential impact level and the associated required actions such as risk assessments, requalification needs, and effectiveness checks. This annexure will serve as a decision-making reference for change initiators and reviewers to ensure uniformity and compliance in the evaluation process.

Target Completion Date: July 30, 2025

9. Revision of Deviation Procedure:

- The Procedure for Handling Deviations (SOP.CQA.0059) will be revised to clearly define the process flow and decision-making criteria for initiating deviations. It will mandate that any GMP-impacting event must trigger a formal deviation. The SOP will explicitly prohibit standalone impact assessments or investigations without an associated deviation, ensuring traceability, QA oversight, and structured risk evaluation.

Target Completion Date: July 30, 2025

10. Revision of Equipment Validation (SOP.CQA.0039):

- The Equipment Qualification SOP will be revised to state:
  - Any critical process parameter (CPP) or critical quality attribute (CQA) of equipment shall be verified during qualification (OQ/PQ) to ensure it aligns with predefined specifications and GMP requirements.
  - Examples include (but not limited to):
    - NVPC alert/action limits (ISO 5/7)
    - Temperature, Relative Humidity, Differential Pressure (for HVAC systems)
    - Conductivity, TOC, pH, Pressure (for water systems)
    - Autoclave temperature and sterilization hold time
    - Recovery time and air velocity (for cleanroom area qualification)

- Verification must be documented using a Configuration Verification Log and jointly approved by User, Engineering and QA.

Target Completion Date: July 30, 2025

11. Alarm Management SOP:

- A dedicated Alarm Management SOP will be prepared or revised to define:
  - Clear classification of alarms (critical, major, minor).
  - Procedures for alarm response, documentation, investigation, and closure.
  - Requirements for periodic review of historical alarms to detect systemic issues or configuration errors.

Target Completion Date: Aug 15, 2025

12. Audit Trail Review:

- A dedicated SOP will be implemented to ensure periodic review of audit trails related to machine engineering parameters, alarm setpoints, and operator interventions.

Target Completion Date: Aug 15, 2025

13. Training:

- Comprehensive training sessions will be conducted for all stakeholders, including QA, Production and Engineering to ensure full understanding of deviation triggers, documentation requirements, and escalation protocols.

Target Completion Date: Aug 15, 2025

Attachments for Observation 1A:

Attachment	:	Document Title
Attachment -1-1	:	Recall Communication and Related Documentation
Attachment -1-2	:	Performance Qualification Report of Vial Filling and Sealing Machine
Attachment -1-3	:	Area Qualification Report
Attachment -1-4	:	Alarm Report of NVP Count of Dara Filling Machine-Lighthouse
Attachment -1-5	:	Alarm Report of NKP Filling Machine
Attachment -1-6	:	Batchwise NVPC Sample Report
Attachment -1-7	:	Impact Assessment Document
Attachment -1-8	:	NVPC Excursion Simulation Study Protocol for Vial Filling and Sealing Machine
Attachment -1-9	:	Interim Report of NVPC Excursion Simulation Study for Vial Filling and Sealing Machine
Attachment -1-10	:	Environmental Monitoring Trend of Q-1
Attachment -1-11	:	Environmental Monitoring Trend of Q-2 (April & May)
Attachment -1-12	:	Historical NVPC Alarm Summary from DARA Automatic Filling Line (Past 24 Months)

Observation No. 2:

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.
Specifically, OOS investigations did not always contain complete written justification to support the root cause and conclusions, and investigations were not always expanded to additional lots when implicated by the root cause.
A) Investigations OOS.23.015 (lot 2304001), OOS.24.001 (lot 2312002), and OOS.23.016 (lot 2310001) identified sample handling and preparation at your contract laboratory as the probable root cause for OOS liquid particle count results in finished drug lots but did not include specific actions by analysts that might have caused the OOS. The contract laboratory investigation did not find any laboratory errors. There was no thorough explanation of the discrepancy between your investigation and your contract laboratory's investigation. There was no record of remedial action at your contract laboratory to prevent reoccurrence of the unspecified root cause. Your firm re-tested these lots and then released and distributed them without identifying the source of the particles found in your drug product.

Tailstorm Health's Response:

Tailstorm acknowledges the FDA's repeat Observation, we also acknowledge these deficiencies reflect gaps in investigation depth, quality oversight of contract laboratories, and internal governance of OOS handling procedures.
Tailstorm Health initiated **Deviation No. DEV-2025-0008** to conduct a comprehensive root cause investigation and develop a corrective and preventive action (CAPA) plan addressing all noted deficiencies. The following response summarizes the OOS results, investigative approach, impact assessment, and structured remediation plan.

Initial Results and OOS Summary

The OOS events noted in this observation pertain to liquid-borne particulate matter results per USP <788> in the following lots:

- Lot 2304001 (Ketamine 10%) – OOS observed during accelerated stability testing at T=6 months *Refer Attachment 2A-1_OOS.23.015 Investigation Report*
- Lot 2310001 and 2312002 (Bupivacaine 0.5% + Epinephrine 5mcg) – OOS reported during release testing *Refer Attachment 2A-2_OOS.23.016_Investigation Report and Attachment 2A-3_OOS.24.001 Investigation Report*

These failures exceeded the acceptance criteria for small volume injections as per USP <788>:

- ≥10 µm, NMT 6,000 particles per container
- ≥25 µm, NMT 600 particles per container

Table – 1 Summary of Initial OOS Results for Particulate Matter per USP <788>

Lot No.	Product	OOS Ref.	Test Orientation / Type	Initial Results		Outcome
				≥10 µm (NMT 6000)	≥25 µm (NMT 600)	
2304001	Ketamine 10%	OOS.23.015	Inverted Accelerated 1	11,630	55	Fail
			Upright Accelerated 1	7,994	33	Fail
			Inverted Real Time 1	10,134	47	Fail
2310001	Bupivacaine 0.5% + Epinephrine	OOS.23.016	Release 1	7,654	28	Fail
2312002	Bupivacaine 0.5% + Epinephrine	OOS.24.001	Release 1	17,646	739	Fail

Initial Investigation Summary of OOS (Year - 2023):

- Phase I Investigations at Eagle Analytical Services (contract testing laboratory) did not identify any analytical or operational errors and did not provide sufficient detail on analyst technique or sample handling.
- Phase II: Tailstorm Health initiated a 6M-based root cause investigation (Man, Method, Machine, Material, Measurement, Mother nature). No specific cause was confirmed.

Repeat Testing Results (Year - 2023):

Retesting was conducted by a qualified second analyst, in duplicate, and all results complied with USP <788> limits

Table – 2 Summary of Repeat Test Results for Particulate Matter per USP <788>

Lot No.	Product	OOS Ref.	Test Orientation / Type	Repeat Test Results		Outcome
				10 µm (NMT 6000)	25 µm (NMT 600)	
2304001	Ketamine 10%	OOS.23.015	Inverted Accelerated 1	2141	67	Pass
			Inverted Accelerated 2	1117	25	Pass
2304001	Ketamine 10%	OOS.23.015	Upright Accelerated 1	939	14	Pass
			Upright Accelerated 2	1020	11	Pass

Lot No.	Product	OOS Ref.	Test Orientation / Type	Repeat Test Results		Outcome
				10 µm (NMT 6000)	25 µm (NMT 600)	
2304001	Ketamine 10%	OOS.23.015	Inverted Real Time 1	304	8	Pass
			Inverted Real Time 2	524	11	Pass
2310001	Bupivacaine 0.5% + Epinephrine	OOS.23.016	Repeat Test Results 1	158	0	Pass
2310001	Bupivacaine 0.5% + Epinephrine	OOS.23.016	Repeat Test Results 2	145	0	Pass
2312002	Bupivacaine 0.5% + Epinephrine	OOS.24.001	Repeat Test Results 1	1661	14	Pass
2312002	Bupivacaine 0.5% + Epinephrine	OOS.24.001	Repeat Test Results 2	1541	29	Pass
2312002	Bupivacaine 0.5% + Epinephrine	OOS.24.001	Repeat Test Results 3	1801	22	Pass

While the retesting results demonstrated product conformance, the lack of a clearly documented specific root cause prior to retesting is acknowledged.

Impact Assessment:

Commercial Life Cycle Evaluation

- All three cited lots were released, distributed, and have since completed their labeled shelf life.
- No adverse events (ADEs), product complaints, or product recalls were associated with any of the three lots.

Stability Study Review

- For Lot 2304001, although the OOS results was observed at T=6 months (accelerated), subsequent testing at T=9 and T=12 months yielded results within specification. *Refer Attachment 2A-4_Stability Data for Lot 2304001*

- This stability trend supports that the lot continued to meet specifications throughout its shelf life.

Historical Review

- A review of all manufactured lots from 2023 to present has shown no other confirmed OOS failures for LPC results.
- This trend suggests that the process and controls in place demonstrate the product is capable of meeting the required particulate limits. *Refer Attachment 2A-5_LPC Data of 2023, 2024 and 2025*

Action Plan:

a. Quality System Enhancements

- Tailstorm Helath will revise SOP.CQC.0042 (Out-of-Specification Handling) to conduct any repeat testing unless a specific and scientifically justified root cause has been established. The revised SOP will include a structured decision-tree to guide investigation pathways, re-testing eligibility, batch disposition, and investigation expansion, aligned with FDA's May 2022 guidance.

- A retrospective review of all QC Analytical OOS investigations conducted over the past 24 months will be performed. This review will re-evaluate the adequacy of root cause determinations, the appropriateness of the CAPAs implemented, and the effectiveness checks carried out to confirm long-term remediation.

- The particulate data obtained from visual inspection of OOS lots will be reviewed and correlated with subvisible particulate matter results to determine if any supporting trends or discrepancies exist between visible and non-visible findings.

- Tailstorm Health will review LPC results from all manufactured lots produced in the past 24 months. The objective is to identify particulate trends and to establish the minimum and maximum ranges for both ≥10 µm and ≥25 µm particles, thereby supporting an evaluation of baseline process variability.

- A trend analysis of stability lots for the same 24 month period will be conducted to confirm that no degradation trends are contributing to subvisible particulate formation during the product shelf life.

- The LPC results of process validation batches will be reviewed to confirm consistency and demonstrate that the validated manufacturing process is capable of consistently producing product within USP <788> specifications.

- Tailstorm Health will evaluate the potential impact of sample orientation and temperature conditions on the LPC results, to determine if these factors contributed to the variability or OOS outcomes.

- A detailed review will be performed on all product contact materials used in the impacted batches. Certificates of Compliance (CoCs) and relevant supplier documentation will be assessed to confirm the integrity and regulatory conformance of these materials.

- A protocol-based hypothesis-driven study will be designed and executed to investigate the extent to which product contact materials contribute to particle generation.

  Target Completion Date: July 30, 2025

b. Strengthening Contract Laboratory Oversight

Tailstorm understand and own the responsibility of all contracted testing and going forward will be significantly strengthening our existing controls in place which governs the testing standards, methods, test result outcome and handling of laboratory events/OOSs:

- Tailstorm Health will conduct an audit of the contract testing laboratory, with a specific focus on LPC test methodology, analyst sample handling practices, laboratory environment control, and completeness of documentation related to OOS investigations.

- The existing Quality Agreement with the contract laboratory will be revised to require the sharing of raw analytical data, analyst observations, and complete investigation reports with Tailstorm. Furthermore, no re-testing of release or stability samples will be permitted at the contract or in-house laboratory unless Tailstorm's Quality Unit has reviewed and approved the root cause, investigation, and resolution plan.

- SOP.CQA.0011 "Qualification and Management of Vendors for GMP Materials and Operations" shall be revised to include a formal quarterly review process by Tailstorm's Quality Unit. This review will evaluate each contract laboratory for the following (but not limited to):
  - Method changes and deviations
  - Specification updates
  - Instrumentation and calibration status
  - OOS results and investigation trends
  - Audit observations and regulatory inspections
  - CAPA implementation status
  - Subcontracting and personnel changes

- A detailed review of LPC testing procedures at the contract laboratory will be performed to evaluate procedural controls, environmental monitoring, equipment qualification, and method execution practices that may influence test accuracy or reproducibility.

- Tailstorm Health will conduct a historical review of LPC related OOS investigations previously conducted at the contract lab to identify recurring issues, trends, or failures in root cause determination and closure.

- The Phase II investigation report provided by the contract laboratory for the cited lots will be re-examined to ensure that no contributing factors were overlooked and that the investigation conclusions are consistent with Tailstorm's internal findings.

  Target Completion Date: August 15, 2025

c. CAPA Planning and Execution

- Based on the consolidated findings from the investigation, Tailstorm Health will define and implement clear, targeted Corrective and Preventive Actions (CAPAs). Each CAPA will include implementation timelines, responsible personnel, and defined measures of effectiveness to ensure long-term resolution of the observed deficiencies.

  Target Completion Date: August 15, 2025

Follow-Up Response to FDA

- Tailstorm Health will submit a complete follow-up report to the FDA within 30 calendar days from the initial response. This report will summarize:

  - Final root cause determination from Deviation DEV-2025-0008
  - Progress and current status of all CAPAs
  - Key outcomes from the historical OOS/OOT investigation review

Attachments for Observation 2A:

Attachment	:	Document Title
Attachment -2A-1	:	OOS.23.015 Investigation Report
Attachment -2A-2	:	OOS.23.016 Investigation Report
Attachment -2A-3	:	OOS.24.001 Investigation Report
Attachment -2A-4	:	Stability Data for Lot 2304001
Attachment -2A-5	:	LPC Data of 2023, 2024 and 2025

Observation No. 2B:

B) Investigations OOS.24.003 (stability lot 2212005, T12_U_CRT), OOS.24.004 (stability lot 2301001, T12_I_CRT), and OOS.23.005 (lots ENG22006 and ENG22007) document multiple bupivacaine assay OOS results for Bupivacaine HCl/Epinephrine Bitartrate injection. Bupivacaine assay was low for one 12-month real-time stability sample, high for one 12-month real-time stability sample, and high for both engineering lots. Your firm determined a weighing or dilution error was the root cause, because the ratio between the standard and sample solution was wider for the OOS lots than passing lots tested at the same time. HPLC system suitability passed, and the laboratory investigation performed by your contract lab did not find any errors. There is no specification or limit for this ratio, and it is not reviewed unless there is a problem with the initial result. Your firm did not expand the investigation to all other lots or even though the root cause identified appears to implicate all assays for this product.

Tailstorm Health's Response:

Tailstorm acknowledges FDA Form 483 Observation which highlights Out of Specification (OOS) assay results for Bupivacaine HCl in Bupivacaine and Epinephrine Bitartrate Injection across both stability and engineering lots. We understand that the observation raised concerns regarding assay variability, adequacy of root cause, and the adequacy of investigation scope.
Tailstorm Health initiated **Deviation No. DEV-2025-0007** to conduct a comprehensive root cause investigation and develop a corrective and preventive action (CAPA) plan addressing all noted deficiencies. The following response summarizes the OOS results, investigative approach, impact assessment, and structured remediation plan.

Clarification of the Reported OOS Events

The reported OOS results originated from both stability and engineering lots tested for Bupivacaine 0.5% and Epinephrine 5 mcg:

- **Low assay values** were reported during T=12-month real-time stability testing for:
  - Lot 2212005 (upright orientation)
  - Lot 2301001 (inverted orientation)

  Refer Attachment 2B-1_OOS.24.003 Investigation Report and Attachment 2B-2_OOS.24.004 Investigation Report

- **High assay values** were reported during T=6-month testing of engineering lots:
  - Lots ENG22006 and ENG22007 (both upright and inverted)

  Refer Attachment 2B-3_OOS.23.005 Investigation Report

Refer to **Table–1 and Table-2** for a complete overview of results and retesting outcomes.

Table – 1 Summary of Initial Test Results for Assay

Lot Number/ OOS Number	Testing Source	Product/Orientation	Stability Condition	Initial Results % Assay Bupivacaine	Pass/ Fail
ENG2206 **OOS.23.005**	Inhouse	Bupivacaine 0.5% and Epinephrine 5mcg	T=6 RT ***Upright***	107.7	Fail
ENG2206 **OOS.23.005**	Inhouse	Bupivacaine 0.5% and Epinephrine 5mcg	T=6 RT ***Inverted***	107.7	Fail
ENG2207 **OOS.23.005**	Inhouse	Bupivacaine 0.5% and Epinephrine 5mcg	T=6 RT ***Upright***	108.3	Fail
ENG2207 **OOS.23.005**	Inhouse	Bupivacaine 0.5% and Epinephrine 5mcg	T=6 RT ***Inverted***	108.5	Fail
221205 **OOS.24.003**	ETX-240112-0118	Bupivacaine 0.5% and Epinephrine 5mcg	T=12 RT ***Upright***	90.4	Fail
2301001 **OOS.24.004**	ETX-240112-0121	Bupivacaine 0.5% and Epinephrine 5mcg	T=12 RT ***Inverted***	90.2	Fail

Table – 2 Summary of Repeat Test Results for Assay

Lot Number/ OOS Number	Testing Source	Product/Orientation	Stability Condition	Retest Results % Assay Bupivacaine	Pass/ Fail
ENG2206 **OOS.23.005**	Inhouse	Bupivacaine 0.5% and Epinephrine 5mcg	T=6 RT ***Upright***	103.1	Pass
ENG2206 **OOS.23.005**	Inhouse	Bupivacaine 0.5% and Epinephrine 5mcg	T=6 RT ***Inverted***	103.4	Pass
ENG2207 **OOS.23.005**	Inhouse	Bupivacaine 0.5% and Epinephrine 5mcg	T=6 RT ***Upright***	102.2	Pass
ENG2207 **OOS.23.005**	Inhouse	Bupivacaine 0.5% and Epinephrine 5mcg	T=6 RT ***Inverted***	103.7	Pass
221205 **OOS.24.003**	ETX-240112-0118	Bupivacaine 0.5% and Epinephrine 5mcg	T=12 RT ***Upright***	99.4	Pass
2301001 **OOS.24.004**	ETX-240112-0121	Bupivacaine 0.5% and Epinephrine 5mcg	T=12 RT ***Inverted***	99.8	Pass

Summary of Root Cause Investigation Findings

A. OOS.23.005 – Engineering Lots (In-house Testing at T=6M)

- Assay values ranged from **107.7% to 108.5%**.
- Review of lab notebooks, HPLC system suitability, and procedural records found no instrumental or documentation errors.
- However, standard area ratios were significantly different from historical norms.
- Re-injection of the original standard and samples reproduced the OOS results.
- A different analyst had prepared the internal standard for the assay standard solution.
- Reanalysis using a freshly prepared standard yielded results within specifications.
- **Conclusion**: An inadvertent dilution error during standard preparation was determined to be the root cause.

B. OOS.24.003 and OOS.24.004 – Stability Lots (Contract Lab at T=12M)

- Initial assay results were 90.2% and 90.4%, triggering OOS.
- Reanalysis using new sample and standard solutions yielded results within the specification (99.4% and 99.8%).
- Contract Lab Phase II Investigation (OOS#240121, 20-Feb-2024) concluded the root cause as:

  "Analytical error while making the sample preparations was concluded to be the cause of the low potency results… likely occurred during spiking of the internal standard."
  Refer Attachment 2B-4_Conclusion Statement of Contract Lab Investigation

- In-house Investigation (29-Mar-2023) corroborated the same root cause:

  "The lower standard ratio might be due to dilution error in standard preparation."

Methodology Overview and Justification

- The % Assay of Bupivacaine is determined using USP-validated Test Method TM.CH.0002, employing Dibutyl phthalate in methanol as the internal standard.

Refer Attachment 2B-5_Test Method (TM.CH.0002)

- Sample and standard preparations undergo weighing, dilution, and HPLC analysis.
- Assay is calculated as:

$$\%Assay = \frac{AT}{AS} \times \frac{WS}{DS} \times \frac{DT}{WT} \times \frac{P}{100} \times \frac{D}{LC} \times 100$$

Where:

- **AT** = Area response ratio in sample,
- **AS** = Area response ratio in standard,
- **WS/WT/DT/DS/P/D/LC** = Weight, dilution, potency, density, and label claim variables

This calculation demonstrates that when the AT/AS ratio is low, the % assay result will also be lower; conversely, when AT/AS is high, the % assay value will be higher. This trend aligns with the results observed during the OOS events. The root cause was confirmed to be variation or error during spiking of the internal standard into either the standard or sample solution.

The AT/AS ratio is a calculated intermediate and Tailstorm Health will now implement an internal trend based control range. Ratios falling outside this range will trigger re-evaluation of test preparations and system suitability before final result acceptance.

Response to Certain FDA Statements in Observation 2B

Tailstorm Helath respectfully provide the following clarification to FDA's Form 483, Observation 2b.

"The laboratory investigation performed by your contract lab did not find any errors."

Tailstorm Health wishes to clarify that this statement does not reflect the complete findings of the contract laboratory. The Phase II investigation report (OOS# 240121, dated 20-Feb-2024) clearly concluded that an error in the internal standard spiking was responsible for the low assay results. This was independently confirmed by Tailstorm's internal investigation.

"There is no specification or limit for this ratio, and it is not reviewed unless there is a problem with the initial result."

Tailstorm Health agrees that the AT/AS ratio used as part of the USP-based assay calculation is a critical component but is not currently subjected to routine evaluation unless an OOS event occurs. However:

- The AT/AS ratio is influenced by the precision in internal standard spiking, analyst technique, and instrument response.

- Tailstorm Health has initiated the establishment of an acceptable range for AT/AS ratio deviations.
- Future analyses will be reviewed against this defined threshold, and testing will be flagged for investigation if the range is exceeded even in the absence of an OOS result.

"Your firm did not expand the investigation to all other lots..."

Tailstorm Health acknowledges this gap. In response:

- A comprehensive review of all released finished product lots and stability lots from 2023 to present has been initiated.
- This review includes analysis of:
  - AT/AS ratio matrix for each lot,
  - System suitability compliance,
  - Assay trends across all tested batches.
- Any lot exhibiting wider-than-acceptable AT/AS deviations will be flagged for detailed review, and assay data will be re-evaluated to determine impact on specification compliance.

Impact Assessment:

- The stability lots mentioned have completed their shelf-life, and no product complaints or adverse events were reported during their lifecycle.
- The engineering lots cited were not released for distribution.

Ongoing and Planned Remedial Actions:

As part of Tailstorm's commitment to continuous improvement and in direct response to Observation 2B, a structured and phased remediation plan has been initiated under **Deviation No. DEV-2025-0007**. The goal of this plan is to address the root causes identified during the investigation of the OOS events, strengthen analytical controls, and ensure that all potentially impacted lots are adequately assessed. The following activities are underway or scheduled for execution:

Action Item	Objective	Target Completion Date
Review of the standard testing procedure (TM.CH.0002)	To review the standard testing procedure, method suitability, and USP acceptance	July 10, 2025

Action Item	Objective	Target Completion Date
	criteria, and correlate with investigation findings to amend procedures as needed.	
Review of literature and evaluation of internal standard-based methods	To identify analytical variability factors and best practices for internal standard methodology	
Perform hypothesis-based calculations to reconfirm the root cause in OOS Lots	To mathematically validate the impact of AT/AS ratio variation on Bupivacaine potency as per USP method	
Process validation batch review	To trend Bupivacaine assay results and establish potency range across process validation lots	
Review of Epinephrine assay in OOS lots	To confirm that Epinephrine results remain compliant and process integrity is unaffected	
Review of Bupivacaine assay from all released product lots (2023–present)	To trend potency data and identify any atypical values among released lots	
Review of Bupivacaine assay from all stability program lots (2023–present)	To trend potency data and identify any atypical values among stability lots	
Review of test method system suitability data for all released lots	To ensure system suitability acceptance criteria were consistently met	
Review of test method system suitability data for all stability lots	To ensure system suitability acceptance criteria were consistently met	
Review of Difference between AT/AS ratio – released lots	To derive a specification for acceptable ratio range for difference between calculated AT and AS	July 25, 2025
Review of Difference between AT/AS ratio–stability lots	To derive a specification for acceptable ratio range for difference between calculated AT and AS	
Design and perform hypothesis experiments for lots exceeding acceptable ratio range	To evaluate potential impact on assay and specification compliance	

Action Item	Objective	Target Completion Date
Derive findings from ratio evaluation and initiate remediation actions	To define appropriate corrective steps for any lots impacted	
CAPA planning and execution	To finalize and implement preventive controls across test method, training, and documentation	

Attachments for Observation 2B:

Attachment	:	Document Title
Attachment -2B-1	:	OOS.24.003 Investigation Report
Attachment -2B-2	:	OOS.24.004 Investigation Report
Attachment -2B-3	:	OOS.23.005 Investigation Report
Attachment -2B-4	:	Conclusion Statement of Contract Lab Investigation
Attachment -2B-5	:	Test Method (TM.CH.0002)

Observation No. 3:

Acceptance criteria for the sampling and testing conducted by the quality control unit is not adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release.

Specifically, we observed multiple deficiencies when we examined your firm's visual inspection, AQL, and particle identification procedures, processes, and executed records.

A) Your firm did not determine the identity, source, and route of contamination for particles and fibers observed inside sterile finished drug vials during 100% visual inspection and AQL performed post-terminal sterilization for lots we examined. The lots met acceptance criteria for VI and AQL and were released with no additional investigation. For example,

- **Inspectors identified 83 units with particles and 16 units with fibers during 100% visual inspection of Sterile Water for Injection, USP 10 mL, lot 2502001.**
- **Inspectors identified 21 units with particles and eight units with fibers during 100% visual inspection of Bupivacaine HCl 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL, lot 2502005.**
- **Inspectors identified five units with particles and four units with fibers during 100% visual inspection of Ketamine 1% 10 mg/mL, 5 mL (SDV), lot 2502008. QA found one additional white fiber during AQL.**
- **Inspectors identified four units with particles and three units with fibers during 100% visual inspection of Ketamine 10% 100 mg/mL, 5 mL (MDV), lot 2502009. QA found one additional white particle during AQL.**
- **Inspectors identified 2 units with particles and 6 units with fibers during 100% visual inspection of Lidocaine HCl 1%/Epinephrine Bitartrate 10 mcg/mL, 10 mL, lot 2503004. QA found one additional white particle and one additional fiber during AQL.**
- **Inspectors identified six units with particles and three units with fibers during 100% visual inspection of Bupivacaine HCl Injection USP 0.25%, 10 mL, lot 2504002**

B) QA inspectors compare rejected defect vials from 100% visual inspection that contain particulates and fibers to the defect gallery

Your current procedures are deficient because they require the QA inspector to visually determine if the particle or fiber is known or unknown and then send the vial for additional identification. There was inadequate explanation how the QA inspector can visually distinguish the composition of similar particles when the description in the defect gallery is a general description such as "black particle". For example, multiple black particles or multiple white fibers will appear similar but might be different materials when examined under microscopy, FTIR, or other identification method. We also noted the procedure applies to defect vials from 100% visual inspection but does not require QA inspectors to compare particles found during AQL to the defect gallery.

C) There is inadequate written justification to classify particulates and fibers found in terminally sterilized injectable drugs as major defects instead of critical defects. Critical defects have a lower defect limit.

D) You do not have adequate written justification for not identifying all particles and fibers observed during 100% visual inspection and AQL

Tailstorm Health's Response:

Tailstorm acknowledges the FDA's observation concerning inadequacies in the identification of particulate matter in the visual inspection process and classification of visible defects. We affirm our strong commitment to aligning all operations with cGMP, pharmacopeial standards and FDA expectations. We have evaluated our current procedures and initiated enhancements to ensure robust control, traceability, and scientific justification for all particulate-related findings. This is a holistic response covering the full lifecycle of particulate detection, classification, and control under Observation 3a, 3b, 3c, and 3d.
We have initiated deviation no. DEV-2025-0009 to determine origin of particulate matter, assess potential impact on product quality, and define appropriate corrective and preventive actions in accordance with our deviation and CAPA procedures.

Observation 3a: Lack of Identification and Source Investigation of Particulate Matter

Current Controls

1. **Incoming Material Inspection:**

   At Tailstorm controls begins with stringent material qualification/verification. Vendor used to procure all primary packaging materials are qualified. All RTU vials, seals, and stoppers are sampled using a statistically justified sampling plan ($\sqrt{n}+1$) as per SOP.CWH.0001. Visual checks ensure exclusion of packaging materials with visible contamination. *Refer Attachment 3-1_SOP.CWH.0001" Receipt, Storage, and Issuance of Materials from Warehouse"*

2. **Post-Cleaning Verification:**

   Post-cleaning, the rinse water used in contact equipment is visually examined for residual particulate, as described in SOP.CMF.0057. This ensures that product-contact surfaces are free from potential particulate sources before batch initiation. *Refer Attachment 3-2_SOP.CMF.0057 "Preparation and Sterilization of the Filling Porous Loads and other Sampling accessories loads"*

3. **Visual Inspection Execution:**

   Following terminal sterilization, 100% visual inspection is performed using semi-automated visual inspection machines by qualified inspectors. Visual inspectors are trained per SOP.CQA.0050, which includes a two-phase qualification: Phase-1 involves defect recognition using a reference defect library, and Phase-2 includes evaluation with vial test set containing ≥10% defect rate. Inspectors must meet predefined accuracy and timing

thresholds. Inspection is governed by SOP.CMF.0042 and is conducted under controlled conditions to ensure consistent defect detection. *Refer Attachment 3-3_SOP.CQA.0050 "Qualification and Re-qualification of Visual Inspection Personnel" and Attachment 3-4_SOP.CMF.0042 "Visible Inspection of Filled Vials for Particles"*

4. **AQL Inspection by QA:**

   QA conducts independent Acceptable Quality Level (AQL) inspection post visual inspection, using Level II or III sampling as per SOP.CQA.0030. The defect limits are:

   - Critical: 0%
   - Major: ≤ 0.40%
   - Minor: ≤ 0.65%

Each control stage ensures exclusion of defective units and supports process monitoring through trending of defect rates. *Refer Attachment 3-5_SOP.CQA.0030 "Acceptable Quality Level"*

Retrospective Review and Trend Analysis:

A retrospective review was performed on the 100% visual inspection data and AQL defect rates for all batches produced during 2024 and 2025. These batches were processed in compliance with established procedures, including post-installation use of the new vial filling, stoppering, and sealing machine (Make: NKP) from 2025 onwards.

100% Visual Inspection and AQL Review

The review confirmed that all batches from both years (2024 and 2025) successfully passed 100% visual inspection and AQL sampling, with defect levels consistently remaining within the defined acceptance thresholds.

No deviations or out-of-limit results were recorded in any batch across the review period.

The consistent results over two years demonstrate a well-established and controlled visual inspection process. Both 100% inspection and AQL checks were effective in identifying and rejecting non-conforming units, ensuring product quality. The trend analysis supports that the visual inspection system, personnel qualification program, and process control strategies were robust and capable of maintaining quality within acceptable limits across all commercial batches during 2024 and 2025. *Refer Attachment 3-6_Visual Inspection Data of Batches Manufactured in 2024-2025"*

Observation 3b: Visual-Only Classification of Particles as Known/Unknown

Current Controls and Identified Gaps:

- SOP.CMF.0042 and SOP.CQA.0030 permitted QA personnel to determine if a defect was "known" or "unknown" based on comparison to a defect gallery. Identification was typically reserved for particles visually classified as "unknown."
- However, as noted, visual-only classification lacks analytical certainty. Fibers or black particles may appear similar but originate from different sources. Additionally, the procedure did not explicitly apply to AQL defects.

Trend and Historical Impact:

No batches released contained visually unidentifiable foreign particles. However, QA identification decisions were not always based on confirmatory analysis.

Observation 3c: Inadequate Justification for Classifying Particulates as Major Instead of Critical Defects

Table – 1 Current Classification

CRITICAL	MAJOR	MINOR
• Broken Vials/ Cracked Vials • Glass Pieces • Metallic/Shining Particles • No rubber Stopper • Content color variation	• High Fill volume • Low Fill Volume • Deformed (mold defect) container • Black Particles • White Particles • Empty Vials • Without Seal • Fiber (White/Black) Particles	• Vials defects (Unremovable stains) • Vial with Black particle in glass • Scratch: Irregular lines on the glass surface • Dented seal • Improper Crimping • Loose Flip Off

Acceptable Limit of 100% visual inspection Rejections:

Defect Gallery	Action
Critical defects 1. Non- Integral physical defects (Broken/Cracked)	0.5 %

Defect Gallery	Action
2. Glass particles 3. Metal particles 4. Content color variation	
Major	1.5 %
Minor	2.0 %
Total	4 %

Defect classification per SOP.CMF.0044 is guided by impact on product safety:

- **Critical**: Direct compromise of container integrity or sterility (e.g., glass pieces, missing stoppers).
- **Major**: Potential for temporary/reversible harm or functional deviation (e.g., visible fiber, particulate contamination).
- **Minor**: Aesthetic issues not impacting safety/efficacy.

Refer Attachment 3-7_SOP.CMF.0044 "Defect Gallery of Vials"

Classification of visible fibers and white/black particles as "Major" was based on prior risk assumptions of low patient impact.

However, current categorization will be updated based on the medical assessment to integrate route of administration and patient safety factors.

Observation 3d: Lack of Written Justification for Not Identifying All Particles

Current Controls

- Historically, known and recurrent particle types (e.g., fiber, glass, sealing debris) observed during visual inspection were not subjected to re-identification. Only unknown particles were analyzed further using FTIR or microscopy to confirm identity.
- This selective approach was designed to maintain efficiency in the inspection workflow; however, it lacked batch specific written justification and scientific documentation for each occurrence.

Trend Analysis and Impact Assessment

A comprehensive retrospective review of 100% visual inspection records and AQL sampling data for 2024 and 2025 was conducted.

Across both years, no batch exceeded acceptance limits for visible particulate matter. No critical defects were observed. Major defects consistently remained <0.40% and minor defects <0.20%, well within control limits. *Refer Attachment 3-6_Visual Inspection Data of Batches Manufactured in 2024-2025"*

No batch showed critical defect presence or trending toward rejection thresholds, and no deviation was observed in either visual inspection or AQL assessment processes.

Liquid Particulate Count (LPC) trend analysis for finished goods confirmed that all measured values remained within the established compendial acceptance criteria, supporting the compliance of batches released. *Refer Attachment 3-8_Subvisible Particle Data of Batches Manufactured in 2024-2025"*

Conclusion: Current system is effective in maintaining product quality. However, enhancements are needed to elevate scientific rigor and ensure regulatory alignment.

Corrective and Preventive Actions (CAPA):

1. Identification and Classification of Particles

- SOP.CMF.0042 and SOP.CHQA.0012 will be revised to ensure:
  - All visual particulate findings during 100% and AQL inspection are reviewed.
  - Particles are categorized into inherent, intrinsic, or extrinsic.
  - Microscopic evaluation by QA and QC is conducted.
  - Comparison with Defect Library using digital microscopy and image-matching software to validate matches (based on color, morphology, birefringence, reflectivity).
  - All recoverable particles, regardless of classification, undergo Microscopy or FTIR or equivalent methods. Advanced analyses (SEM-EDS, Raman, XRD) will be used when necessary.

Target Completion Date: July 30, 2025

2. Creation of Particle Identification Library

- Develop a centralized FTIR/Raman/microscopy spectrum library for:
  - Packaging components (vials, rubbers, seals)
  - Equipment contact materials
  - Environmental materials (fibers, lint, etc.)
  - Historical process contaminants or batch rejects

Target Completion Date: August 15, 2025

3. Baseline Data Compilation, Trending and Thresold Establishment

- Establish a baseline by identifying all particles over a defined period using a statistically meaningful and representative data set for each product group.
- This data will be used to establish a baseline that reflects normal particle incidence rates by type and origin
- Frequency of individual particle types will be trended over time to identify abnormal variation
- Based on this baseline, we will define particle-specific Alert Limits (for increased scrutiny) and Action Limits (which will trigger investigation, source identification, and batch hold/quarantine where necessary)
- Trending will enable root cause prioritization and support ongoing material source mapping, enhancing our ability to proactively mitigate recurring issues.

Target Completion Date: To be determined upon sufficient batch data availability

4. Escalation of Extrinsic or Out-of-Limit Particles

Following the establishment of baseline particle trends and thresholds, each instance of particle detection whether during 100% visual inspection or AQL will be subjected to a structured evaluation process:

- All visual rejections will first undergo digital microscopic examination by trained QA and QC personnel. Morphological characteristics such as shape, structure, color, and surface texture will be compared against the defect gallery using high-resolution imaging and matching software.
- If a particle's visual and morphological features match a known category and fall within the established baseline and alert limit, it will be logged accordingly for trend analysis but not escalated for chemical identification.
- If a particle:
    - Exhibits a new or uncharacteristic morphology (e.g., unexpected shape, color, or texture), or
    - Exceeds the particle-specific alert or action limits derived from the baseline study, or
    - Cannot be confidently categorized based on visual features alone, then the unit will be flagged for analytical identification.

- Such samples will be:
    - Quarantined immediately.
    - Sent for FTIR analysis, and if required, advanced techniques such as SEM-EDS, Raman spectroscopy, or XRD.
    - Investigated for root cause using equipment logs, gowning records, and environmental monitoring data.

- In cases where a known particle type is detected at a frequency beyond its action limit or appears under suspicious or unexpected conditions, a deviation will be raised. A full investigation will be initiated regardless of prior classification.

This structured escalation strategy ensures that any potential contamination event whether due to recurring or novel particulates is systematically evaluated and addressed in compliance with cGMP expectations.

Target Completion Date: To be determined upon sufficient batch data availability

5. Defect Categorization Revision Based on Medical Risk

Tailstorm will revise its defect classification methodology to integrate medical and clinical risk assessments. This enhanced risk-based categorization will be established in collaboration with pharmacovigilance and clinical affairs experts to ensure patient safety is the foremost criterion.

- Each particle type observed during inspections will be evaluated based on:
    - **Route of administration** (e.g., intravenous [IV], intramuscular [IM]), as IV-administered drugs inherently carry higher particulate risk.
    - **Dosage form configuration** (e.g., SDV vs. MDV), where patient exposure frequency and cumulative risk may vary.
    - **Toxicological profile** of the identified material using scientific literature, in-house studies, or vendor data.
    - **Clinical impact profile**: Differentiating reversible/localized effects (e.g., irritation) from systemic or irreversible risks (e.g., embolism, immune reaction).
- SOP.CMF.0044 will be revised to reflect this risk-based reclassification.

Target Completion Date: July 30, 2025

6. Batch Disposition Descision

Batch disposition will be governed by a scientifically robust, risk-based decision-making process that evolves in two distinct phases: prior to baseline establishment and after its completion.

- **Phase 1 – Until Baseline Establishment:**
    - During the initial implementation phase, all recoverable particulate matter observed during 100% visual inspection or AQL will be subjected to complete analytical identification using microscopy and FTIR or equivalent.
    - Only particles confirmed to be inherent or intrinsic in nature will be considered acceptable for trending and classification.

- Any particle that is extrinsic, morphologically unrecognized, or for which chemical composition cannot be confirmed, will trigger a deviation and full impact assessment before any disposition.

- **Phase 2 – After Baseline Establishment and Threshold Definition:**
  - Once a comprehensive baseline is created, particle evaluation will be streamlined as follows:
    - **Step 1: Microscopy-Based Evaluation**
      - All visual rejections will undergo microscopy evaluation by QA/QC.
      - Particles will be compared against the Defect Gallery.
    - **Step 2: Within Alert Level and Matched to Library**
      - If the particle's morphology matches a known defect and occurrence is within its alert limit, it will be logged for trend analysis. No further chemical identification is required.
    - **Step 3: Alert Limit Exceeded**
      - If the occurrence exceeds the alert limit or displays discrepancies in morphology, the particle will undergo FTIR or equivalent analytical identification.
    - **Step 4: Action Limit or Unknown Particle**
      - If any known particle exceeds the action limit, or a particle remains morphologically or chemically unclassified:
        - A deviation will be raised.
        - QA will assess batch impact in accordance with SOP.CQA.0018.
        - CAPA will be implemented based on findings.
    - **Step 5: Final Disposition**
      - Batch disposition (release or rejection) will occur only after:
        - Identification of particulates.
        - Source and nature confirmation (inherent/ intrinsic/ extrinsic).
        - Trend review against defined thresholds.

Target Completion Date: To be determined upon sufficient batch data availability

Tailstorm Health trusts this comprehensive response demonstrates our commitment to continuous improvement and regulatory compliance. While our historical performance supports the effectiveness of our current controls, we recognize the importance of enhancing scientific

justification, traceability, and process rigor. All corrective actions will be executed under a formal CAPA framework and verified through effectiveness checks.

Attachments for observation 3:

Attachment	:	Document Title
Attachment -3-1	:	SOP.CWH.0001 Receipt, Storage, and Issuance of Materials from Warehouse
Attachment -3-2	:	SOP.CMF.0057 Preparation and Sterilization of the Filling Porous Loads and other Sampling accessories loads
Attachment -3-3	:	SOP.CQA.0050 Qualification and Re-qualification of Visual Inspection Personnel
Attachment -3-4	:	SOP.CMF.0042 Visible Inspection of Filled Vials for Particles
Attachment -3-5	:	SOP.CQA.0030 Acceptable Quality Level
Attachment -3-6	:	Visual Inspection Data of Batches Manufactured in 2024-2025
Attachment -3-7	:	SOP.CMF.0044 "Defect Gallery of Vials
Attachment -3-8	:	Subvisible Particle Data of Batches Manufactured in 2024-2025

Observation No. 4:

Routine inspection and checking of equipment is not performed according to a written program designed to assure proper performance.

Specifically, we observed the UV lamp unit on your water for injection (WFI) generation skid leaking and creating a puddle on the floor on 05/14/25. There were no records available to determine how long this leak was present. Your firm uses WFI to produce approximately 19 different terminally sterilized injectable drugs. Examples of lots produced with WFI include: Sterile Water for Injection, USP 10 mL, lot 2502001; Bupivacaine HCl 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL, lot 2502005; Ketamine 10% 100 mg/mL, 5 mL (MDV), lot 2502009; and Bupivacaine HCl Injection USP 0.25%, 10 mL, lot 2504002.

Tailstorm Health's Response:

Tailstorm Health acknowledges the FDA's Observation regarding the Water for Injection (WFI) system leak observed at the UV lamp sleeve assembly within the WFI generation unit. This condition could potentially compromise the microbiological integrity of the WFI system and could adversely affect product quality if unaddressed.
A thorough investigation has been completed. The company has identified the root cause and implemented corrective and preventive actions (CAPAs). An impact assessment has also been conducted to verify that no product was affected. Details of the investigation and subsequent actions are outlined below.

Background

On May 14, 2025, prior to the FDA investigator's walkthrough of the Water for Injection (WFI) area, the Engineering Supervisor identified a minor water leak originating from the UV lamp sleeve assembly of the WFI generation unit. The issue was proactively documented, and a breakdown report (CH/ENG/2025/0003) was initiated by the Engineering department at 10:00 AM, in accordance with internal deviation and breakdown reporting procedures. *Refer Attachment #1 Breakdown Maintenance Requisition Form.*

Subsequently, during FDA's facility inspection on the same day, at approximately 1:00 PM, investigators also observed the same leak during their visit to the WFI generation system area. This observation was noted and documented as part of the FDA's findings.

Investigation

Following the initiation of breakdown report CH/ENG/2025/0003 on May 14, 2025, the Engineering team conducted a structured investigation to determine the source, extent, and potential impact of the WFI leakage.

The investigation included the following immediate actions:

a. User Notification & Usage Control

- The production team was informed immediately upon detection, and the use of WFI from the affected generation system was halted pending investigation and repair.

b. System Shutdown

- The WFI generation unit was safely powered down to prevent any further leak and allow for prompt maintenance.

c. UV Unit Isolation and Drainage

- The UV lamp assembly was mechanically isolated.
- The UV chamber was drained to facilitate internal inspection and maintenance.

d. Component Disassembly and Examination

- The terminal caps of the UV lamp were disassembled.
- Inspection revealed a worn O-ring gasket between the quartz sleeve and UV chamber housing.

This evidence supported the identification of a mechanical seal failure as the asignable root cause.

In parallel with the ongoing FDA inspection, the identified leak was promptly corrected during the inspection window itself. The UV lamp sleeve assembly O-ring was replaced, and the system was sanitized post-repair. All related documentation including the closed breakdown record (CH/ENG/2025/0003), WFI system sanitization records, and WFI test results confirming compliance with microbial and chemical specifications were reviewed onsite by the FDA investigator and submitted as part of the inspection process.

Impact Assessment

A comprehensive impact assessment was conducted to evaluate the effect of the leak on WFI usage, product quality, and environmental conditions. The assessment considered operational, quality, microbiological, and engineering aspects.

a. Operational Status of WFI System:

- At the time of leak detection, the WFI was not in use for any manufacturing process.
- The WFI system was being utilized in cleaning operations of the production area.

b. Microbial and Contamination Risk Controls:

- The WFI generation and distribution system undergoes a weekly hot water sanitization as per SOP.CEN.0001, to prevent potential microbial presence. *Refer Attachment 4-2 Operation and Sanitization of WFI Generation and Distribution System.*
- Review of system records confirmed that the most recent sanitization was conducted on May 11, 2025. *Refer Attachment 4-3 Sanitization Record of WFI System.*
- The system sanitization was performed following the repair. *Refer Attachment 4-4 Sanitization Record of WFI System.*

c. Preventive Maintenance Verification

- As per the Monthly Preventive Maintenance Schedule (SOP.CEEN.0001-F13), a visual inspection for any leaks in the WFI generation system is required.
- The last preventive maintenance was conducted on April 24, 2025, and inspection records confirmed that no abnormalities or leaks were observed at that time. *Refer Attachment 4-5 Preventive Maintenance Record of WFI System*
- Since the leak was observed on May 14, 2025, it can be concluded that the leak occurred between April 24 and May 14, 2025.
- There were no product batches manufactured after April 17, 2025, thereby mitigating the risk of product impact from the leak.

d. WFI Quality Monitoring and Compliance:

- Engineering executed sanitization of the Water for Injection (WFI) generation system immediately after repair. This was carried out as per SOP.CEN.0001 to restore full microbiological control of the WFI system before it was returned to operational status.
- Online monitoring records for Conductivity and Total Organic Carbon (TOC) remained within the acceptable USP <1231> limits during the time period surrounding the event.
- Conductivity at the EDI outlet and TOC levels in the return loop were recorded every 2 hours for 3 consecutive days post-repair. *Refer Attachment 4-6 Online Parameter Monitoring Record*
- All values were within acceptable limits per USP <1231>, confirming system stability and WFI quality.
- Offline testing was conducted after the leak repair was performed and confirmed that Bacterial Endotoxins Test (BET), Bioburden, Conductivity and Description met specification.

e. Environmental Monitoring (EM):

- As the WFI was used for area cleaning, a detailed retrospective review of environmental monitoring data was conducted for the respective zones.
- Results of Settle Plate Sampling, Air Sampling, and Contact Plate Sampling for the days before, during, and after the incident were reviewed.
- All EM results were found within alert and action limits, confirming that no environmental contamination occurred from the WFI use. *Refer Attachment 4-7 Environmental Monitoring Trend of Q1-2025 and Attachment 4-8 Environmental Monitoring Trend of Q2-2025(April & May)*

f. Utility System Integrity:

- The leak was confirmed to be isolated to a single point (UV lamp O-ring) and did not affect the loop integrity.
- The positive pressure in the loop ensured that no external contaminants could enter the system during the leak event.

g. System Usage Timeline:

- The last batch manufactured prior to the incident was on April 17, 2025.
- No production activities took place between April 17 and May 14, 2025.

Conclusion of Impact Assessment:

Based on the above evaluations:

- There was no impact on product quality or patient safety.
- There was no impact on facility cleaning effectiveness.
- There was no impact on the microbiological integrity of the environment.
- The issue as an isolated mechanical failure

The WFI remained compliant with quality standards and safe for continued use in cleaning and subsequent operations.

Retrospective Review of Breakdowns in Utilities (2024-2025)

a. WFI System

A retrospective review of WFI system breakdowns and preventive maintenance activities was performed for the period of January 2024 to May 2025 to determine if any other leaks were observed prior to May 14, 2025.

- Records confirm that the only recorded breakdown associated with the WFI generation and distribution system during this period is the current incident, documented under Breakdown Report CH/ENG/2025/0003.
- This confirms that the event is an isolated mechanical failure rather than a systemic or recurring problem.

The preventive maintenance activities performed on the WFI system include monthly checks, all of which contain a checkpoint for visual inspection of potential leaks as per SOP.CEEN.0001-F13.

Table-1 Preventive Maintenance Data of WFI System

Preventive Maintenance Date	Observation Summary
26-Jan-2024	No leak or abnormality observed
23-Feb-2024	No leak or abnormality observed
29-Mar-2024	No leak or abnormality observed
26-Apr-2024	No leak or abnormality observed
24-May-2024	No leak or abnormality observed
28-Jun-2024	No leak or abnormality observed
29-Jul-2024	No leak or abnormality observed
30-Aug-2024	No leak or abnormality observed
27-Sep-2024	No leak or abnormality observed
29-Oct-2024	No leak or abnormality observed
29-Nov-2024	No leak or abnormality observed
27-Dec-2024	No leak or abnormality observed
24-Jan-2025	No leak or abnormality observed
24-Feb-2025	No leak or abnormality observed
24-Mar-2025	No leak or abnormality observed
24-Apr-2025	No leak or abnormality observed (last PM before leak)

This detailed review provides strong assurance that:

- The leakage occurred after April 24, 2025, the last PM where the system was visually inspected.
- No prior leaks or mechanical faults were reported for the WFI system.
- The current issue is therefore confirmed as non-recurring and isolated.

b. HVAC System

The HVAC system has been reviewed to determine preventive controls and alarm systems in place:

- The system is equipped with controls that continuously monitor temperature, relative humidity (RH), and differential pressure (DP).

- Any disturbance in the environmental parameters due to instrument failure or system malfunction triggers an automated alert system that is addressed immediately by Engineering personnel.
- Preventive maintenance is carried out according to:
    - **SOP.CEEN.0001-F21** – Quarterly Preventive Maintenance of AHU *Refer Attachment 4-9*
    - **SOP.CEEN.0001-F22** – Semi-Annual Preventive Maintenance of AHU *Refer Attachment 4-10*
- These PMs include tasks such as:
    - Visual inspection for leaks or mechanical damage in ducting.
    - Filter cleaning and replacement as per operational hours or condition.
    - Motor and blower performance checks and verification of control system alarms.

Conclusion: The HVAC system has robust monitoring and maintenance procedures, ensuring continued environmental integrity and no history of leaks or malfunction that could impact product quality.

c. Compressed Air and Nitrogen Systems

The compressed air and nitrogen systems were reviewed in terms of construction integrity, monitoring controls, and preventive maintenance effectiveness.

- Both systems use welded stainless steel (SS) piping without manual joints or connections, significantly reducing the likelihood of leaks.
- Manufacturing equipment such as Compounding Tanks, Vial Filling and Sealing Machine and Autoclave includes automated alarms and interlock systems that monitor pressure parameters. Any low pressure alarm trigger alerts for immediate investigation.
- The Semi-annual Preventive Maintenance (PM) of Compressed Air System (SOP.CEEN.0001-F24) includes steps:
    - "Ensure no leaks from the connections of the air receiver tank using soap solution"
    - "Ensure healthy condition of the filters installed at the discharge line of the air compressor; replace if any abnormalities are found" *Refer Attachment 4-11*
- Similarly, the Semi-annual PM of the Nitrogen Generation System (SOP.CEEN.0001-F16) includes detailed verification actions:
    - "Check pneumatic valves and air piping connections for any wear, tear, or leaks; if observed, take necessary corrective actions"

- "Ensure no leaks from the N2 output connections, inlet of the N2 buffer tank and receiver, and outlet of the N2 receiver and buffer tank" *Refer Attachment 4-12*

These SOP-driven activities confirm that leak detection is systematically monitored and corrective measures are pre-defined. As per retrospective Preventive Maintenance records, no leaks or abnormalities have been reported in these systems during the 2024–2025 period.

Conclusion: The integrity of the WFI and other critical systems is supported by their robust mechanical design, comprehensive maintenance SOPs, and reliable monitoring and alert mechanisms, all of which serve to mitigate the risk of failure or contamination. No breakdown events or deviations have been reported in the retrospective review period.

Corrective Actions and Preventive Actions

To address the root cause of the leak and prevent recurrence, Tailstorm Health has implemented and initiated the following corrective and preventive actions:

The Standard Operating Procedure (SOP) SOP.CEN.0001-F01 governing the operation logbook of the WFI generation and distribution system was revised and implemented on June 03, 2025. This revision introduced a mandatory checkpoint for daily visual verification of potential leaks across all components of the WFI system. This enhancement is intended to ensure real-time detection and timely correction of any future mechanical failures. **Status:** Completed

Refer Attachment 4-13 Operation logbook of the WFI generation and distribution system

Furthermore, the SOP will be subjected to a second revision, which will include clear and structured action steps to be taken in the event of leak, visible damage, and replacement of any component parts. This addition will further strengthen response efficiency and ensure that all deviations are handled consistently and thoroughly. **Target Completion Date**: June 30, 2025

Attachments for Observation 4:

Attachment	:	Document Title
Attachment -4-1	:	Breakdown Maintenance Requisition Form
Attachment -4-2	:	Operation and Sanitization of WFI Generation and Distribution System
Attachment -4-3	:	Sanitization Record of WFI System
Attachment -4-4	:	Sanitization Record of WFI System
Attachment -4-5	:	Preventive Maintenance Record of WFI System
Attachment -4-6	:	Online Parameter Monitoring Record
Attachment -4-7	:	Environmental Monitoring Trend of Q1-2025

Attachment	:	Document Title
Attachment -4-8	:	Environmental Monitoring Trend of Q2-2025(April & May)
Attachment -4-9	:	SOP.CEEN.0001-F21 – Quarterly Preventive Maintenance of AHU
Attachment -4-10	:	SOP.CEEN.0001-F22 – Semi-Annual Preventive Maintenance of AHU
Attachment -4-11	:	SOP.CEEN.0001-F24 - Semi-annual Preventive Maintenance (PM) of Compressed Air System
Attachment -4-12	:	SOP.CEEN.0001-F16 - Semi-annual PM of the Nitrogen Generation System
Attachment -4-13	:	SOP.CEN.0001-F01 - Operation logbook of the WFI generation and distribution system

Observation No. 5A:

Buildings used in the manufacturing, processing and packing of a drug product are not maintained in a good state of repair.

Specifically, we observed maintenance deficiencies with the cleanrooms production technicians use to manufacture all terminally sterilized injectable drugs including: Sterile Water for Injection, USP 10 mL, lot 2502001; Bupivacaine HCl 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL, lot 2502005; Ketamine 10% 100 mg/mL, 5 mL (MDV), lot 2502009; and Bupivacaine HCl Injection USP 0.25%, 10 mL, lot 2504002.

A) We observed multiple pieces of apparent autoclave tape under the conveyor belt and on the wall surrounding the outlet from the sealing and capping station of the ISO 5 RABS filling line into the ISO 7 autoclave room. There was no written explanation of why the tape was present or how long it was present.

Tailstorm Health's Response:

Tailstorm Health acknowledges the FDA's observation regarding the presence of autoclave tape within a classified cleanroom environment, specifically around the outlet of the sealing and capping station from the ISO 5 RABS filling line to the ISO 7 autoclave room.

Deviation No. DEV-2025-0006 was initiated to document and investigate this nonconformance in alignment with our quality system procedures.

Immediate Action

- On May 13, 2025, immediately following the FDA investigator's walkthrough, a manufacturing technician visited the autoclave room (PR009), removed all visible autoclave tape near the conveyor outlet and wall, and sanitized the affected surfaces with 70% IPA.

- An immediate inspection of the ISO 5 RABS filling line and adjacent classified spaces including the ISO 7 filtration room, compounding room, change rooms, pass boxes, conveyor belt, and autoclave room was conducted. No other anomalies or unauthorized foreign materials were detected.

Investigation

- An investigation was initiated following the finding by the investigator. The autoclave room (PR009) was evaluated, and personnel involved in routine area cleaning were interviewed. During interviews, it was noted that a gamma-irradiated trash bag may have been temporarily secured using autoclave tape to prevent it from shifting during cleaning activities.

- The technician involved clarified that the tape was applied as a one-time action during a routine cleaning task, and not as part of a recurring or instructed practice. The action occured based on perceived convenience in managing bag stability during waste handling.
- The investigation found no evidence of habitual or systemic use of autoclave tape for such purposes. No records, deviation reports, or prior inspection findings suggested recurrence of this issue. This incident appears to have resulted from isolated action taken during a routine cleaning task.
- No SOP or work instruction endorsed or referenced the use of autoclave tape for waste handling or wall attachment. Therefore, this incident was determined to be a result of behavioral oversight during daily cleaning activity, compounded by the lack of targeted visual inspections post cleaning.
- The root cause was determined to be behavioral oversight during daily cleaning activities, combined with the absence of a dedicated structure for waste bag placement and the lack of inspection criteria post-cleaning.

Impact Assessment

A comprehensive impact assessment concluded that the presence of the autoclave tape had no adverse effect on product quality, environmental integrity, or patient safety. Key findings include:

- No product or open containers were present in the autoclave room during the time of inspection.
- The observed autoclave tapes were not in direct contact with any product or critical equipment surfaces.
- The tape used was cleanroom-compatible (silicone-based adhesive) and known not to leave residue, thereby minimizing risk to surface integrity.
- The area was sanitized following standard cleaning procedures under SOP.CMF.0050 using Decon Spore.
- A proactive visual inspection of all cleanrooms (ISO 5, 7, and 8) was conducted. No additional unauthorized tape or similar maintenance deviations were identified.
- Differential pressure gradients between ISO 5 and ISO 7 were confirmed to be compliant, with positive airflow cascading from the ISO 5 sealing area through the transfer hatch into the ISO 7 autoclave room. This airflow direction was confirmed during the facility's most recent smoke study (airflow visualization), which clearly showed that laminar flow from the ISO 5 RABS environment passes into the ISO 7 area, thereby preventing backflow of air and

minimizing the risk of contamination to the ISO 5 critical area. *Refer Attachment 5A-1 Air Flow Visualization Report*

- Environmental Monitoring (EM) data for the autoclave room (ISO 7) showed all active air samples taken on May 5, 16, and 21, 2025, reported 0 CFU. *Refer Attachment 5A-2 Environmental Monitoring Trend Q2-2025 (April & May)*
- Transfer of sealed vials from ISO 5 to ISO 7 via the mouse hole does not pose contamination risk, as no open product is exposed during transfer.

Conclusion: Based on physical evidence, pressure cascading and microbiological data, this issue posed no impact to product quality, sterility assurance, or environmental classification.

Corrective and Preventive Actions

Tailstorm Health implemented immediate corrective measures including removal of the autoclave tape and sanitization of the affected area. A facility wide inspection confirmed no other instances of tape or other foreign materials.

As a part of facility improvement, waste bag stands have been introduced in all cleanroom areas to provide a proper and compliant solution for securing waste bags during cleaning or operations.
Target Completion Date: July 15, 2025

SOP.CMF.0050 will be revised to include post-cleaning visual checks and escalation in case of any facility related issues. Cleanroom staff will undergo training to reinforce material handling expectations and escalations.
Target Completion Date: July 15, 2025

SOP.CHQA.0002 "Line Clearance" will be revised to includes checks for non-designated items.
Target Completion Date: July 15, 2025

Attachments for Observation 5A:

Attachment	:	Document Title
Attachment -5A-1	:	Air Flow Visualization Report
Attachment -5A-2	:	Environmental Monitoring Trend Q2-2025 (April & May)

Observation No. 5B:

Buildings used in the manufacturing, processing and packing of a drug product are not maintained in a good state of repair.

Specifically, we observed maintenance deficiencies with the cleanrooms production technicians use to manufacture all terminally sterilized injectable drugs including: Sterile Water for Injection, USP 10 mL, lot 2502001; Bupivacaine HCl 0.5%/Epinephrine Bitartrate 5 mcg/mL Injection, 10 mL, lot 2502005; Ketamine 10% 100 mg/mL, 5 mL (MDV), lot 2502009; and Bupivacaine HCl Injection USP 0.25%, 10 mL, lot 2504002.

B) We observed a missing electrical outlet cover in the ISO 7 autoclave room with an apparent black substance surrounding the entire outlet. There was no written explanation of how long the outlet cover was missing or the identity of the black substance.

Tailstorm Health's Response:

Tailstorm Health acknowledges the FDA's observation. We understand the critical importance of maintaining all facility infrastructure especially within classified cleanroom environments in a state of good repair. We recognize that an exposed or damaged electrical outlet within an ISO 7 room could pose both particulate and microbial contamination risks and may compromise cleanroom integrity if not promptly identified and mitigated.

Deviation No. DEV-2025-0006 was initiated to document and investigate this nonconformance in alignment with our quality system procedures.

Immediate Action

Upon notification of the investigators finding, the following actions were executed immediately to ensure personnel safety and to eliminate contamination risks:

- Operators were promptly instructed to avoid contact with the affected area to eliminate potential electrical and contamination risks.
- The exposed outlet was immediately covered using a sterile, cleanroom compatible Tyvek wrap to prevent ingress of particulates or microbial contaminants.
- A qualified engineer was instructed to assess and replace the missing cover with a cleanroom compatible socket cover.
- The autoclave room (PR009) was immediately cleaned and disinfected per SOP.CMF.0050 using Decon Spore.

Investigation Summary

1. Cause of Missing Outlet Cover:

The investigation concluded that the outlet cover was inadvertently dislodged and broken due to physical contact likely from material handling equipment (such as a cart). The outlet is located at a height and position that makes it susceptible to incidental contact during routine operational activities.

2. Identification of Black Substance:

The black substance observed surrounding the outlet was identified as a portion of the polycarbonate cover itself, not residue or contamination. This was confirmed by:

- Visual comparison with undamaged socket units in similar areas.
- Cross-referencing the manufacturer's technical data sheet, which confirms that the cover is constructed from high impact, cleanroom compatible polycarbonate material. *Refer Attachment 5B-1 Technical Specification of Electrical Outlet*

3. Environmental and Product Safety Considerations:

- No in-process or exposed product was present in the autoclave room at the time of the observation.
- The exposed outlet area was located outside of ISO 5 zones and was confirmed to have positive pressure differentials maintained from ISO 5 to ISO 7, thus reducing the risk of backflow or cross-contamination.
- Environmental Monitoring (EM) data collected on May 5, 16, and 21, 2025, for the autoclave room (PR009) reported 0 CFUs, confirming no microbial impact from the outlet condition. *Refer Attachment 5B-2 Environmental Monitoring Trend Q2-2025 (April & May)*

4. Cleaning and Disinfection:

Post-identification, the area was immediately disinfected per the routine cleaning procedure SOP.CMF.0050, using sporicidal disinfectants (Decon Spore). The outlet was subsequently replaced with a new cleanroom compatible cover.

5. Facility-wide Inspection:

Following the incident, a facility-wide inspection of all cleanroom zones (ISO 5, 7, and 8) was conducted to identify any similar maintenance issues. No other exposed or uncovered electrical fixtures were found across inspected areas, including corridors, airlocks, compounding area, dispensing area and vial filling area.

6. Procedural Gaps Identified:

While cleaning and area maintenance were conducted in accordance with existing SOPs, it was determined that the current cleaning SOP lacks a defined escalation or verification step to identify and report facility related infrastructure issues such as missing outlet covers or damaged fixtures. This procedural gap delayed the recognition and formal documentation of the missing outlet cover.

Root Cause Evaluation:

The missing outlet cover was the result of unintentional mechanical damage during routine operations. The black material observed was confirmed to be the polycarbonate component of the outlet cover itself, verified through visual evidence and technical datasheet references. The material posed no risk to cleanroom integrity or product quality, and the area was cleaned and sanitized immediately following identification. However, the absence of a formal post-cleaning facility verification and escalation step in the SOP was identified as a contributing factor to the issue remaining unreported.

Impact Assessment

- **Product Exposure:**
  - The autoclave room handles only sealed containers during terminal sterilization staging.
- **Material Compatibility:**
  - The material identified around the outlet was confirmed to be polycarbonate, part of the original outlet cover.
  - It is suitable for use in ISO classified spaces and poses no contamination risk.
- **Environmental Monitoring:**
  - EM data collected on May 5, 16, and 21, 2025 from the autoclave room (PR009) showed 0 CFU from active air samples.
  - Results confirmed the absence of microbial contamination during the period in question. *Refer Attachment 5B-2 Environmental Monitoring Trend Q2-2025 (April & May)*
- **Airflow and Pressure Differential:**
  - ISO 5 zones maintained positive differential pressure relative to the ISO 7 autoclave area.
  - Airflow studies confirm a cascading airflow preventing cross-contamination into critical zones. *Refer Attachment 5B-3 Air Flow Visualization Report*
- **Facility-Wide Condition Inspection:**
  - A full inspection of all ISO 5, 7, and 8 areas at the facility and found no other exposed or uncovered electrical sockets.

Based on the investigation, there was no impact on product quality, environmental integrity, or patient safety. The black substance was confirmed to be cleanroom-compatible polycarbonate, and no contamination or microbial risk was identified.

Corrective Action and Preventive Action

SOP.CMF.0050 will be revised to include a mandatory post-cleaning facility condition verification step. The updated SOP will instruct cleaning personnel to escalate any observed maintenance related issues through initiation of a General Work Requisition Form as per SOP.CEEN.0012.
Target Completion Date: July 15, 2025

Cleanroom operators, supervisor and cleaning crew will undergo retraining to ensure awareness of escalation protocols and infrastructure integrity checks.
Target Completion Date: July 15, 2025

Facility Maintenance SOP (SOP.CEEN.0012) will be revised to change the inspection frequency from quarterly to monthly for cleanrooms, and the inspection checklist will be updated to include comprehensive coverage of infrastructure related elements such as wall fixtures, electrical outlets, doors, lights, floor and panel integrity.
Target Completion Date: July 15, 2025

Attachments for Observation 5B:

Attachment	:	Document Title
Attachment -5B-1	:	Technical Specification of Electrical Outlet
Attachment -5B-2	:	Environmental Monitoring Trend Q2-2025 (April & May)
Attachment -5B-3	:	Air Flow Visualization Report

4Z

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH01802	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Noramco LLC

Physical Address: 500 Swedes Landing Rd

City: Wilmington State: DE Zip: 19801

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 302-888-4485 Website: www.noramco.com

Name of Designated Representative (DR): Tracey Lorraine Norton [redacted]ell

Licensing Company Email: tnorton@noramco.com DR Email: tnorton@noramco.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	■ Dangerous Drugs	■ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Finished Dosage Form Manufacturers		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*: N/A

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Tracey L. Norton
Original Signature (electronic, copies or stamps not accepted)

4-23-2026
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year. N/A Note - Noramco is an active ingredient manufacturer - we make the starting material for finished dosage forms.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation N/A

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: GA

Parent Company (if any): Noramco US Holdings, Inc

Corporation/Organization Name: Noramco, LLC

Mailing Address: 500 Swedes Landing Road

City: Wilmington State: DE Zip: 19801

Telephone: 302-888-4485 [redacted] Email: tnorton@noramco.com

Contact Person Name: Tracey Norton

Section 6: Partnership N/A

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner N/A

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)			✓	
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Noramco LLC

Facility Name

Tracey L. Norton

Print Name of Authorized Person Submitting Application

Tracey L. Norton

Original signature of Authorized Person (copies or stamps not accepted)

4-23-2026

Date

Board Use Only	Date Received: 5/5/26	Amount: $1000 ck 37998

Drug Establishments Current Registration Site

Share Tweet Linkedin Email Print

New Search

Search Results for **Noramco**

CSV Excel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Noramco, LLC	2522445	166506142	API MANUFACTURE; PARTICLE SIZE REDUCTION; REPACK;	500 Swedes Landing Road, Wilmington, Delaware (DE) 19801, United States (USA)	12/31/2026

Showing 1 to 1 of 1 entries

Previous 1 Next

Data Current through: Monday, Apr 20, 2026

Return to Drug Firm Annual Registration Status Home Page

Once FTC Approval is received for Siegfried to purchase Noramco US Holdings, Inc., Corporate Officers for Noramco, LLC (500 Swedes Landing Road, Wilmington, DE 19801) will be the following.

100% of Noramco, LLC is owned by Noramco US Holdings, Inc. Officers do not own Noramco, LLC. Noramco US Holdings, Inc. is not publicly traded.

William Bayne Grubb III, President

[redacted]

Anthony Ambrosini, Vice President

[redacted]

Michael C. Schultz, Treasurer

[redacted]

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "NORAMCO, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTEENTH DAY OF MAY, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "NORAMCO, LLC" WAS FORMED ON THE THIRTIETH DAY OF NOVEMBER, A.D. 2019.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

7725474 8300

SR# 20261676501

Authentication: 203940625

Date: 05-15-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

NOT TRANSFERABLE

STATE OF DELAWARE
DIVISION OF PROFESSIONAL REGULATION

CANNON BUILDING
861 SILVER LAKE BLVD., SUITE 203
DOVER, DELAWARE 19904-2467

PROFESSIONAL LICENSE

PROFESSION:	Pharmacy
LICENSE TYPE:	Pharmacy - Manufacturer
LICENSE NUMBER:	A5-0000071
LICENSE STATUS:	Active
ISSUE DATE:	05/16/2016
EXPIRATION DATE:	09/30/2026
ISSUED TO:	Noramco
PHYSICAL ADDRESS:	500 SWEDES LANDING ROAD WILMINGTON DE 19801
SIGNATURE:	_____

THIS CERTIFIES THAT THE PERSON NAMED IS HEREBY LICENSED TO
CONDUCT OR ENGAGE IN THE PROFESSION INDICATED ABOVE.
THIS DOCUMENT IS DULY ISSUED UNDER THE LAWS OF THE STATE OF DELAWARE

Department of State
Division of Professional Regulation
Our mission is to credential qualified professionals to ensure the protection of the public's health, safety, and welfare

Online Services

The Division of Professional Regulation is proud of our professional and responsive customer service. To receive renewal notices and other critical information, be sure to keep your professional license contact information up-to-date.

To manage your license, log into DELPROS. Visit our web site at dpr.delaware.gov for essential reference information and 24/7 access to online services.

Can't find what you need online? Send an email to customerservice.dpr@delaware.gov and let us know what you need.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	10-31-2026	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N	MANUF (BULK)	01-27-2026

NORAMCO
500 SWEDES LANDING RD
WILMINGTON, DE 198014417

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	10-31-2026	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
1,2,2N, 3,3N	MANUF (BULK)	01-27-2026

NORAMCO
500 SWEDES LANDING RD
WILMINGTON, DE 198014417

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 1086005

Application/License No. _____

Noramco, LLC
_____, doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
500 Swedes Landing Road, Wilmington, DE 19801
_____, as
Address of Applicant/Principal
PRINCIPAL, and The Hanover Insurance Company
_____, a
Surety Company
corporation organized under the laws of the state of New Hampshire
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
440 Lincoln Street Worcester, MA 01653
_____ as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of FIVE THOUSAND DOLLARS ($5,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on January 2, 2021.
Effective Date

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $5,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 a[illegible]y costs incurred by the Board regarding the license of Applicant/Principal t[illegible]ose pursuant to NRS 622.400 or 622.410 which the Applicant/Princi[illegible]

Company has been licensed with us for more than 5 years.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 18th day of November, 2020.

APPLICANT/PRINCIPAL

COMPANY
Noramco, LLC

Authorized Representative

NANCY A. BYE
NOTARY PUBLIC
STATE OF DELAWARE
MY COMMISSION EXPIRES JANUARY 30, 2022

SIGNED and SEALED in the presence of:

Witness Nancy A Bye

Witness Miguel Gonzalez

SURETY
The Hanover Insurance Company

Surety Company's Representative

Catharina Hardy, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness James Janner

Witness Yauheniya Romina

Countersigned by:

Nevada Resident Agent
Michael Turner, License#45914

THE HANOVER INSURANCE COMPANY
MASSACHUSETTS BAY INSURANCE COMPANY
CITIZENS INSURANCE COMPANY OF AMERICA

POWER OF ATTORNEY

THIS Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

KNOW ALL PERSONS BY THESE PRESENTS:

That THE HANOVER INSURANCE COMPANY and MASSACHUSETTS BAY INSURANCE COMPANY, both being corporations organized and existing under the laws of the State of New Hampshire, and CITIZENS INSURANCE COMPANY OF AMERICA, a corporation organized and existing under the laws of the State of Michigan, (hereinafter individually and collectively the "Company") does hereby constitute and appoint,

Brenna Page Tuccelli, Barry R. Page, Bonnie Robbins, Candy Leifker, Taylor Pollock, Catharina Hardy and/or Craig Sanassarian

Of **Insurance Office of America dba IOA Insurance Services of Sacramento, CA** each individually, if there be more than one named, as its true and lawful attorney(s)-in-fact to sign, execute, seal, acknowledge and deliver for, and on its behalf, and as its act and deed any place within the United States, any and all surety bonds, recognizances, undertakings, or other surety obligations. The execution of such surety bonds, recognizances, undertakings or surety obligations, in pursuance of these presents, shall be as binding upon the Company as if they had been duly signed by the president and attested by the secretary of the Company, in their own proper persons. Provided however, that this power of attorney limits the acts of those named herein; and they have no authority to bind the Company except in the manner stated and to the extent of any limitation stated below:

Any such obligations in the United States, not to exceed Ten Million and No/100 ($10,000,000) in any single instance

That this power is made and executed pursuant to the authority of the following Resolutions passed by the Board of Directors of said Company, and said Resolutions remain in full force and effect:

RESOLVED: That the President or any Vice President, in conjunction with any Vice President, be and they hereby are authorized and empowered to appoint Attorneys-in-fact of the Company, in its name and as it acts, to execute and acknowledge for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, waivers of citation and all other writings obligatory in the nature thereof, with power to attach thereto the seal of the Company. Any such writings so executed by such Attorneys-in-fact shall be binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company in their own proper persons.

RESOLVED: That any and all Powers of Attorney and Certified Copies of such Powers of Attorney and certification in respect thereto, granted and executed by the President or Vice President in conjunction with any Vice President of the Company, shall be binding on the Company to the same extent as if all signatures therein were manually affixed, even though one or more of any such signatures thereon may be facsimile. (Adopted October 7, 1981 – The Hanover Insurance Company; Adopted April 14, 1982 – Massachusetts Bay Insurance Company; Adopted September 7, 2001 – Citizens Insurance Company of America)

IN WITNESS WHEREOF, THE HANOVER INSURANCE COMPANY, MASSACHUSETTS BAY INSURANCE COMPANY and CITIZENS INSURANCE COMPANY OF AMERICA have caused these presents to be sealed with their respective corporate seals, duly attested by two Vice Presidents, this 23rd day of **October, 2020**.

The Hanover Insurance Company
Massachusetts Bay Insurance Company
Citizens Insurance Company of America

John C. Roche, EVP and President

The Hanover Insurance Company
Massachusetts Bay Insurance Company
Citizens Insurance Company of America

James H. Kawiecki, Vice President

THE COMMONWEALTH OF MASSACHUSETTS)
COUNTY OF WORCESTER) ss.

On this 23rd day of **October, 2020** before me came the above named Vice Presidents of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, to me personally known to be the individuals and officers described herein, and acknowledged that the seals affixed to the preceding instrument are the corporate seals of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, respectively, and that the said corporate seals and their signatures as officers were duly affixed and subscribed to said instrument by the authority and direction of said Corporations.

DIANE J. MARINO
Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
March 4, 2022

Diane J. Marino, Notary Public
My Commission Expires March 4, 2022

I, the undersigned Vice President of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, hereby certify that the above and foregoing is a full, true and correct copy of the Original Power of Attorney issued by said Companies, and do hereby further certify that the said Powers of Attorney are still in force and effect.

GIVEN under my hand and the seals of said Companies, at Worcester, Massachusetts, this 18th day of November 2020

CERTIFIED COPY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Noramco, LLC dba Noramco

Pharmacy/Wholesaler License # (if applicable): WH01802

Physical Address: 500 Swedes Landing Rd.

City: Wilmington State: DE Zip: 19801

Mailing Address (if different from physical address): SAME

City: State: Zip:

Telephone: 302-888-4485 Website: www.noramco.com

Licensing Company Email: tnorton@noramco.com

Section 2: Personal Information

First: Tracey Middle: Lorraine Last: Norton

Alias(es, nicknames, name changes, etc.): —

Date of Birth: [redacted] SSN or ITIN: N/A Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Bethlehem State: PA Zip: 18020

Telephone: [redacted] Email: tnorton@noramco.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name See attached resume.			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY) 2004-Current	[redacted]	City Bethlehem	State PA	Zip [redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: find attached resume			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours: 6000 +	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Continue on next page if additional space is needed.

TRACEY L. NORTON

[redacted]

OBJECTIVE: To apply my pharmaceutical compliance expertise and leadership skills in a way that helps the company maintain and improve upon its compliance through successful regulatory inspections and agency interactions.

EXPERIENCE:

5/2018 – present *Noramco, 500 Swedes Landing Road, Wilmington, DE 19801*

Director, Controlled Substance Compliance & Security

- Oversee all DEA compliance and Security activity for the Wilmington and Athens sites. This includes working with DEA on imports, exports, quota, SOM, disposal and 222 forms to name a few. Responsible for assuring State licensing and SOPs are current and applicable to the business. Oversees contract guard force, submits requests and monitors installation and upkeep of security equipment. Hosts DEA inspections and participates in internal and customer audits as needed.

8/2017- 5/2018 *Neos Therapeutics, 2940 N. Highway 360, Grand Prairie, TX 75050*

Compliance Manager

- Remote position; traveled to site one week/month. Position managed facility state and federal licensing program, suspicious order monitoring, product stewardship activities, departmental budget, provided subject matter expertise on all other DEA/State matters including quota, inventory management, SOPs, recordkeeping, inspections, etc.

11/2016-8/2017 *Self-Employed, Pennsylvania Based*

Regulatory Consultant

- Provide regulatory expertise to various pharmaceutical companies regarding State and DEA licensing, regulatory inspections, standard operating procedures and day-to-day operations as well as conducting routine facility audits or mock inspections.

12/2014-3/2016 *H. D. Smith Wholesale Drug, 3201 W. White Oaks Dr., Springfield, IL 62704*

VP, Regulatory Compliance & Security

- Company leader responsible for eight different wholesale distribution sites and one 3PL facility. Locations in IL (2), TX, NJ, CA (2), KY, FL, NH
- Supervised field and in-house personnel responsible for providing organizational regulatory support, conducting internal audits, pharmacy audits, regulatory reporting, suspicious order monitoring, recalls, licensing and agency requests.
- Partnered with vendors and construction personnel regarding security and safety matters across the divisions.

8/2011-12/2014 *Qualitest Pharmaceuticals, Inc., 130 Vintage Drive, Huntsville, AL 35763*

Director, DEA Compliance

- Member of the twelve-person Operations Leadership Team responsible for key decisions and strategic initiatives for the Huntsville, AL and Charlotte, NC sites.
- Responsible for all aspects of DEA Compliance for these sites.
- Development of the complete DEA program including design, hiring and mentoring of DEA Compliance group members, creation of an operational structure within Manufacturing and the Warehouse to prevent diversion, design of the employee training plan, oversight of DEA reporting, quota and SOP creation, providing guidance on ERP and WMS systems, creation of strategic plans and risk management assessments and development of the company's suspicious order monitoring program.

3/2010-8/2011 *Reckitt Benckiser, Inc., 399 Interpace Parkway, Parsippany, NJ 07054*

Compliance Manager, Regulatory Affairs Department

- Responsible for developing a compliance program to assure all sample activities regulated by FDA's Prescription Drug Marketing Act were met (for Reckitt Benckiser this included List I chemicals also regulated by DEA)
- System validation of Target Mobile System for Sales Representatives
- Coordinated all State compliance activities related to wholesale distribution of medical devices, OTC products, cosmetics and List I (handled Rx and Controlled Substances in past).
- Interpreted state aggregate spend requirements, developed company's program & training.
- Compliance officer responsibilities as described in the OIG Compliance Program Guidance

6/2002-8/2009 *Watson Laboratories, Inc., 360 Mt. Kemble Avenue, Morristown, NJ 07962*

Director of Controlled Substance Compliance

- Managed the controlled substance activities of eleven different manufacturing, research, analytical laboratory and distribution facilities, including four to six direct reports and a budget of just over $1M
  - Signatory authority for import/export permits and declarations, 222 order forms and registrations that did not require a Corporate Officer
  - Responsible for overseeing State, DEA and VAWD requirements, including fingerprinting, surety bonds, home state verifications and designated representatives
  - Designed database to manage 400+ DEA and State Registrations (dist., mfg., sales)
  - Supervised the internal audit function which performed routine site assessments that led to significant compliance improvements (DEA, PDMA, GMP, Ethics, Investigations)
- Performed complex analysis of existing regulations and pending federal legislative bills; recognized resident subject matter expert on DEA regulations
  - Suspicious Order Monitoring
  - Ryan Haight Act – Internet Pharmacies
  - Electronic Prescribing
  - Drug Disposal Initiatives
- Prepared detailed analytical summaries and timely responses to industry-related issues that had a direct impact on the company's business model and profitability
  - Researched and authored position paper that led to the development of the company's controlled substance import strategy
  - Created talking points and presentations utilized in high level quota negotiations and compliance matters with DEA and State agencies
  - Developed and delivered proactive, timely and results-driven training for employees at all levels
  - Collaborated with others in industry to drive favorable policy formation
- Provided guidance and refined the company's regulatory policy through the authoring of several standard operating procedures:
  - Theft/loss reporting, tableting & encapsulating machine transfers, 222 form processing, registration processing, internal audits, quota requests, ARCOS reporting, imports and exports, etc.
- Oversaw and directed quota applications for Schedule II and List I chemicals
  - Supervised the development of spreadsheets to effectively track purchases, quota requests, approvals, sales and forecasts for commercial products
- Successfully completed several product development, scale-up and/or transfer initiatives with no compliance issues
- Represented the organization with federal and state regulatory agencies
  - Liaison for site inspections; responsible for maintaining an excellent rapport with members of DEA Field and HQ Offices as well as peer groups and industry associations

4/1987-6/2002 *Novartis Pharmaceuticals, Inc. 59 Route 10, East Hanover, NJ 07936*

DEA/PDMA Manager (1997–2002)

- Provided a primary contact for the Pharmaceuticals Division with federal agencies such as the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) on all issues concerning the Controlled Substances Act of 1970 and the Prescription Drug Marketing Act (PDMA) of 1988.
- Acted as a consultant to the division for issues associated with these regulations (i.e. quota, ARCOS, import/export, 222 forms, in-transit losses/thefts, returns/disposals, etc.).
- Interpreted and applied existing regulations and reviewed and monitored proposed rulemaking
- Performed internal audits, inventories and investigations of applicable departments at all three sites and external audits of suppliers, contract packagers and fulfillment houses.
- Actively participated in investigations related to potential diversion and/or the performance of sales representatives
- Coordinated DEA or FDA inspections pertinent to these regulations at all three sites
- Supervised development of controlled drug reporting systems such as ARCOS or SOMs (Suspicious Order Monitoring)
- Submitted theft and/or loss reports to DEA/FDA
- Served on various project teams (e.g. Ritalin Batch Record Project Team, Warehouse Integration Team)
- Participated in the creation of print materials for multiple controlled product Education Campaigns (input, review, approval, dissemination)
- Supervised DEA/PDMA Specialist

Compliance Analyst I/II (1992-1997)

- Sole trainer for the Pharma Division in DEA regulations
- Coordinated DEA and State Registrations
- Oversaw, and in some cases conducted yearly controlled substance inventories for three sites
- Submitted various reports to DEA, FDA or State agencies.

Regulatory Analyst (1989-1992)

- Prepared and submitted promotional material to the FDA
- Assured the accurate submission of Drug Listings to FDA for all products
- Maintained the customer complaint database for all products (both medical and technical)
- Worked with various regulatory agencies to resolve import issues

EDUCATION:

- Seton Hall University, South Orange, NJ – Corporate Healthcare Compliance Certificate – 2010
- University of Florida, Gainesville, FL - Masters in Pharmacy (Pharmaceutical Policy & Regulation) - May 2010. Courses focused on brand/generic drug approval, FDA, DEA and State regulations, Risk Evaluation and Mitigation Strategies (REMS), DDMAC/promotion and advertising, Medicare/Medicaid and private insurance, quality of care initiatives, comparative effectiveness testing and case law supporting each. GPA: 4.0
- Muhlenberg College, Easton, PA - B.A., Business Administration, with honors – 2001. GPA: 3.8
- Previously held ASQ Certified Quality Auditor (CQA) & AQP Certified Facilitator Certificates

ASSOCIATIONS:

NADDI Member, Member of the NASCSA 2009 Resolutions Committee, Previous Consultant NASCSA State Profile Project, Midwest Discussion Group Member, N.J. Pharmaceutical Industry Working Group, Anti-Diversion Industry Working Group (Red Flags Video/NABP)

REFERENCES: Available upon request.

See resume.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

N/A

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Tracy L. Norton

Original Signature (electronic, copies or stamps not accepted)

4-23-2026

Date

I, Tracey Lorraine Norton, **certify that as the designated representative for**

Noramco, LLC dba Noramco,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TN I am at least 21 years of age;
3. TN I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TN I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TN I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TN I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TN I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Tracey Norton

Print Name (First, Last)

Tracey Norton

Original Signature (electronic, copies or stamps not accepted)

4-23-2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tracey Norton
Print Name (First, Last)

Tracey L. Norton — 4/21/2026
Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Delaware, ss. County of New Castle

I, Tracey Norton, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Tracey Norton — 4/21/2026
Original Signature — **Date**

Subscribed and Sworn to before me this 21st day of April 2026

Mary K Coleman
Notary Public Signature



Note - Corporate Officer but does not own greater than 10%.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site NORAMCO, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) WH01802

Physical Address 500 SWEDES LANDING RD

City WILMINGTON State DE Zip 19801

Mailing Address (if different from physical address) SAME

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email tnorton@noramco.com

Section 2: Personal Information

First WILLIAM Middle BAYNE Last GRUBB III

Alias(es, nicknames, name changes, etc.) BILL

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City HIGHLANDS State NC Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: GEORGIA STATE UNIVERSITY			From - To (MM/YY – MM/YY): 9/89 - 6/91	
Address: 33 GILMER ST	City: ATLANTA		State: GA	Zip: 30303
Diploma/Degree obtained, if any: B.S. CHEMISTRY AND PHYSICS				
School Name: UNIVERSITY OF GEORGIA			From - To (MM/YY – MM/YY): 9/86 - 3/89	
Address: 325 TATE STUDENT CENTER	City: ATHENS		State: GA	Zip: 30602
Diploma/Degree obtained, if any:				
School Name: GLYNN ACADEMY			From - To (MM/YY – MM/YY): 1/85 - 5/86	
Address: 1001 MANSFIELD ST	City: BRUNSWICK		State: GA	Zip: 31520
Diploma/Degree obtained, if any: HIGH SCHOOL DIPLOMA				
School Name: NEWPORT HIGH SCHOOL			From - To (MM/YY – MM/YY):	
Address: 4333 FACTORIA BLVD, SE	City: BELLEVUE		State: WA	Zip: 98006
Diploma/Degree obtained, if any:				
School Name:			From - To (MM/YY – MM/YY	
Address:	City:		State:	Zip:
Diploma/Degree obtained, if any:				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
6/22 - WHEE	[redacted]	HIGHLANDS	NC	[redacted]
- 6/22		WILMINGTON	DE	
10/20 - 6/22		EAST GREENWICH	RI	
8/17 - 10/20		WILMINGTON	DE	
4/13 - 8/17		ATHENS	GA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: NORAMCO LLC			From - To (MM/YY – MM/YY): 04/97 - CURRENT
Business Address: 500 SWEDES LANDING RD	City: WILMINGTON	State: DE	Zip: 19801
Phone	Title: VP CORPORATE DEVELOPMENT & COMPLIANCE		
Description of Duties: MANAGE COMPLIANCE FOR DEA AND ~~FA~~ FDA QUALITY AND REGULATORY AFFAIRS.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

WILLIAM B. GRUBB III

Print Name (First, Last)

William B. Grubb IV

Original Signature (electronic, copies or stamps not accepted)

4.21.2026

Date

Please have this section completed in the presence of a Notary Public.

State of DELAWARE, ss. County of NEW CASTLE

I, WILLIAM B. GRUBB III, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

William B. Grubb III

Original Signature

4.23.2026

Date

Subscribed and Sworn to before me this 23 day of April 2026.

Natalie Harvey

Notary Public Signature

Natalie Christine Harvey
State of Delaware
Notary Public
Commission No. 20241115000015
My Commission Expires 11/15/2026

(Seal)

Note - Corporate Officer but does not own greater than 10%.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Noramco, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) WH01802

Physical Address 500 Swedes Landing Road

City Wilmington State DE Zip 19801

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email tnorton@noramco.com

Section 2: Personal Information

First ANTHONY Middle _____ Last AMBROSINI

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITI [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City PHILADELPHIA State PA Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
WEST CHESTER UNIVERSITY		01/93 - 12/95	
Address	City	State	Zip
700 SOUTH HIGH STREET	WEST CHESTER	PA	19383
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
TEMPLE UNIVERSITY		09/85-05/89	
Address	City	State	Zip
1801 N BROAD ST	PHILADELPHIA	PA	19122
Diploma/Degree obtained, if any			
BACHELOR OF SCIENCE - BUSINESS			

School Name		From - To (MM/YY – MM/YY)	
ST JOSEPH'S PREPARATORY HIGH SCHOOL		09/81-05/85	
Address	City	State	Zip
1733 W GIRARD AVE	PHILADELPHIA	PA	19130
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/03-PRESENT	[redacted]	PHILADELPHIA	PA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
NORAMCO			07/16 - PRESENT
Business Address	**City**	**State**	**Zip**
500 SWEDES LANDING ROAD	WILMINGTON	DE	19801
Phone	**Title**		
302-761-2902	VP COMMERCIAL OPERATIONS		

Description of Duties

RESPONSIBLE FOR ALL SALES FORECASTING AND DEVELOPMENT. MANAGE THE CUSTOMER SERVICCE ORGANIZATION. REPORTS. BOARD MEMER OF NORAMCO.

Business Name			From - To (MM/YY – MM/YY)
JOHNSON & JOHNSON			10/99-06/16
Business Address	**City**	**State**	**Zip**
ONE JOHNSON & JOHNSON PLAZA	NEW BRUNSWICK	NJ	08933
Phone	**Title**		
732-524-0400	CONTROLLER		

Description of Duties

FINANCE LEAD AND ACCOUNTING MANAGER FOR SEVERAL BUSINESS IN THE J&J NETWORK. MANAGED ACCOUNTING STAFF AND RESPOSIBLE FOR FINANCIAL REPORING AND ANALYSIS.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ANTHONY AMBROSINI

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/23/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Delaware, ss. County of New Castle

I, Anthony Ambrosini, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4-23-26

Date

Subscribed and Sworn to before me this 23 day of April 2026.

Notary Public Signature

Natalie Christine Harvey
State of Delaware
Notary Public
Commission No. 20241115000015
My Commission Expires 11/15/2026

(Seal)

Note - Corporate Officer but does not own greater than 10%.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Noramco, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) WH01802

Physical Address 500 Swedes Landing Road

City Wilmington State DE Zip 19801

Mailing Address (if different from physical address) SAME

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email tnorton@noramco.com

Section 2: Personal Information

First MICHAEL Middle C Last SCHULTZ

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 500 Swedes Landing Road

City Wilmington State DE Zip 19801

Telephone [redacted] Email mschultz@noramco.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Yale School of Management		08/10 - 05/12	
Address	**City**	**State**	**Zip**
165 Whitney Ave	New Haven	CT	06511
Diploma/Degree obtained, if any			
Masters in Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Saint Joseph's University		08/02 - 05/06	
Address	**City**	**State**	**Zip**
5600 City Ave	Philadelphia	Pa	19131
Diploma/Degree obtained, if any			
Bachelor of Science in Accounty			

School Name		From - To (MM/YY – MM/YY)	
Unionville High School		08/98 - 06/02	
Address	**City**	**State**	**Zip**
750 Unionville Road	Kennett Square	Pa	19348
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/13 - Present	[redacted]	West Chester	Pa	[redacted]
From - To (MM/YY – MM/YY)		City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Noramco			01/01 – present	
Business Address		**City**	**State**	**Zip**
500 Swedes Landing Rd		Wilmington	De	19801
Phone	**Title**			
302-652-3840	CFO, Group Controller			
Description of Duties				
Financial Close and Forecasting/Analysis				

Business Name			From - To (MM/YY – MM/YY)	
Chemours			07/15 – 01/01	
Business Address		**City**	**State**	**Zip**
1007 N Market Street		Wilmington	De	19801
Phone	**Title**			
302-773-1000	Senior Finance Manger			
Description of Duties				
Global cost accounting and analysis				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Schultz
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/23/26
Date

Please have this section completed in the presence of a Notary Public.

State of Delaware, ss. County of New Castle

I, Michael Schultz, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/23/26
Date

Subscribed and Sworn to before me this 23 day of April, 2026.

Notary Public Signature

Natalie Christine Harvey
State of Delaware
Notary Public
Commission No. 20241115000015
My Commission Expires 11/15/2026

(Seal)

Noramco, LLC

Payroll Name	Job Title Description	Location Description
Adcock, John Paul	SR. WAREHOUSE SPECIALIST	Wilmington Plant
Aldana, Jennifer	Associate Manager	Wilmington Plant
Allen, Edward J	SENIOR MAINTENANCE TECHNICIAN	Wilmington Plant
Allen, Elizabeth J	CSC Specialist	Wilmington Plant
Ambrosini, Anthony	VP, Business Development	REMOTE
Anusiem, Onyebuchi Felix	SR. QA SPECIALIST	Wilmington Plant
Baksh, Jasmin M	ADMINISTRATIVE ASSISTANT	Wilmington Plant
Baroud, Riad	Director Information Technology	Wilmington Plant
Battersby, Scott Wagner	SENIOR MANUFACTURING OPERATOR	Wilmington Plant
Baylis, Daniel J	LEAD MANUFACTURING OPERATOR	Wilmington Plant
Bell, George H	SENIOR MANUFACTURING OPERATOR	Wilmington Plant
Bey, Alexander R	LEAD MANUFACTURING OPERATOR	Wilmington Plant
Blocksom, Kenneth A	MANUFACTURING SUPERVISOR	Wilmington Plant
Blyskal, Andrew J	Senior Process Safety Management Engineer	Wilmington Plant
Boyd, Danielle M	Senior Detailed Scheduler	Wilmington Plant
Boyd, Jeffrey	Operations Trainer	Wilmington Plant
Boyle, Christopher J	Senior Wastewater Treatment Plant Operator	Wilmington Plant
Bretschneider, William R	Staff Process Engineer	Wilmington Plant
Brown, Ethen J	QC LAB ANALYST	Wilmington Plant
Burns, Emily Anne	QUALITY ANALYST - TRAINING SYSTEMS	Wilmington Plant
Caltagirone, Dennis D	SENIOR MANUFACTURING OPERATOR	Wilmington Plant
Cardoso, Anajelly	Associate Manager	Wilmington Plant
Cardot, Jessica	PROJECT MANAGER REGULATORY AFFAIRS	REMOTE
Caruso, Andrew J	Senior Director Financial Planning & Analysis	REMOTE
Cavender, Douglas B	SR FACILITIES SPECIALIST	Wilmington Plant
Christiansen, Patricia A	SENIOR BUYER	Wilmington Plant
Clark, Kevin L	CO-OP UNDERGRADUATE	Wilmington Plant
Coia, Nicholas A	CO-OP UNDERGRADUATE	Wilmington Plant
Coleman, Kourtney M	Security Lead	Wilmington Plant
Coleman, Mary K	Associate Manager Payroll/Benefits	Wilmington Plant
Collacchi, Ashley R	QC CHEMIST	Wilmington Plant
Conner, Colleen K	Manager Analytical R&D	Wilmington Plant

Cooper, Christopher G	Lead Business Analyst	Wilmington Plant
Counsellor, Austin J	MANUFACTURING OPERATOR	Wilmington Plant
Cox, Aletrius Ladonne	PROJECT MANAGER REGULATORY AFFAIRS	REMOTE
Craft, Michael Joseph	Maintenance Technician	Wilmington Plant
Craft, Robert	Compliance Specialist Operations	Wilmington Plant
Craig, Daryl M	MANUFACTURING OPERATOR	Wilmington Plant
Craig, Jonathan M	MANUFACTURING OPERATOR	Wilmington Plant
D'Elia, Ryan C	QC CHEMIST	Wilmington Plant
Davis, Randall N	SENIOR PROCESS SCIENTIST	Wilmington Plant
DeHaven, Jesse J	MANUFACTURING OPERATOR	Wilmington Plant
Deforrest, Eric R	Sr Cost Accountant	Wilmington Plant
Delgado, Carlos L	MANUFACTURING OPERATOR	Wilmington Plant
Duong, Chris Y	QA SPECIALIST	Wilmington Plant
Ehrhardt, Robert	STAFF EXECUTION SYSTEMS ENGINEER	Wilmington Plant
Ellis, Kevin C	SENIOR PROCESS ENGINEER	Wilmington Plant
Eye, Raymond J	LEAD MAINTENANCE TECHNICIAN	Wilmington Plant
Ezzarhouni, Nisrine	CO-OP UNDERGRADUATE	Wilmington Plant
Fenwick, William G	CO-OP UNDERGRADUATE	Wilmington Plant
Flamer-Sorrell, Stefan R	ASSOCIATE MANUFACTURING OPERATOR	Wilmington Plant
Foster, Dylan S	MANUFACTURING OPERATOR	Wilmington Plant
Frunzi, Alex	LEAD MANUFACTURING OPERATOR	Wilmington Plant
Furbush, Antwan A	ASSOCIATE MANUFACTURING OPERATOR	Wilmington Plant
Furbush, Woodrow A	Lead Warehouse Operator	Wilmington Plant
Gantert, Danielle M	SR. TECHNICAL SERVICES SPECIALIST	REMOTE
Gardner, Milton Stanley	Senior Wastewater Treatment Plant Operator	Wilmington Plant
Gasby, Gacobi G	Security Lead	Wilmington Plant
Goodlin, Michael J	SENIOR BUYER	Wilmington Plant
Graham, Antonio D	MANUFACTURING OPERATOR	Wilmington Plant
Grant, Ryan R	MANUFACTURING OPERATOR	Wilmington Plant
Grant, Shane E	MANUFACTURING OPERATOR	Wilmington Plant
Grubb, William B	Vice President Compliance & Corporate Develop	REMOTE
Guro, James F	Director, Quality Assurance, Quality Systems	Wilmington Plant
Haden, Nathan A	Staff Process Engineer	Wilmington Plant
Hadfield, John R	LEAD MAINTENANCE TECHNICIAN	Wilmington Plant

Haemmerle, Jessica Susan	Associate Manager	REMOTE
Haemmerle, Ryan M	Operations Director	Wilmington Plant
Halford, Nathan C	QC LAB ANALYST	Wilmington Plant
Hanus, Daniel E	Maintenance Technician	Wilmington Plant
Harris, Richard P	MANUFACTURING OPERATOR	Wilmington Plant
Harrison, Jacqueline Marie	MANAGER, QUALITY ASSURANCE	REMOTE
Hehn, Paul J	Assistant Group Controller	REMOTE
Heisler, David J	SENIOR FINANCE MANAGER	REMOTE
Herman, Amber Marie	MANAGER CUSTOMER SUPPLY SERVICE	REMOTE
Hindsley, Ryan H	ASSOCIATE MANUFACTURING OPERATOR	Wilmington Plant
Hogan, Robert R	STAFF PROCESS SCIENTIST	Wilmington Plant
Holmes, Christie A	Director Supplier and Program Management	REMOTE
Husyev, Mykola	MANUFACTURING OPERATOR	Wilmington Plant
Irwin, Kenneth C	MANUFACTURING SUPERVISOR	Wilmington Plant
Jackson, Rachel M	Associate Director Quality Control	Wilmington Plant
Jaeger, Olivia M	SR QC LAB ANALYST	Wilmington Plant
James, Karen E	Sr. Director Reg Affairs & Tech Svcs	REMOTE
Johnson, Quinton E	MANUFACTURING OPERATOR	Wilmington Plant
Joyce, Erin L	Senior CSC Specialist	REMOTE
Keller, Alexander M	WAREHOUSE OPERATOR	Wilmington Plant
Keller, Matthew B	MANUFACTURING SUPERVISOR	Wilmington Plant
Khokhal, Samir D	SENIOR PROCESS ENGINEER	Wilmington Plant
Lang, Stephen Carl	QC TECH SPECIALIST	Wilmington Plant
Laskos, Jonathan B	Project Manager Maintenance	Wilmington Plant
Lattomus, Mark A	ASSOCIATE MANUFACTURING OPERATOR	Wilmington Plant
Lawson, Jeremy T	PROCESS ENGINEER	Wilmington Plant
Lewis, Celeste I	Security Supervisor	Wilmington Plant
Lopez, Delfin C	LEAD MAINTENANCE TECHNICIAN	Wilmington Plant
Lu, Ronghua	SENIOR PROCESS SCIENTIST	Wilmington Plant
Luciano, Marc T	LEAD MANUFACTURING OPERATOR	Wilmington Plant
Magid, Matthew A	MANUFACTURING OPERATOR	Wilmington Plant
Mannaa, Sherouk	SR QC LAB ANALYST	Wilmington Plant
Marsh, Joseph L	Senior Manager Plant Engr&Maint	Wilmington Plant
Marshall, Melisa L	QUALITY ASSURANCE COORDINATOR	Wilmington Plant

Massari, Mariano	OPERATIONS MANAGER	Wilmington Plant
McCarson, Nathan D	SR QC LAB ANALYST	Wilmington Plant
McCullough, Michael W	Staff Reliability Engineer	Wilmington Plant
McFadden, Jada N	QA SPECIALIST	Wilmington Plant
Miller, Adam C	LEAD MAINTENANCE TECHNICIAN	Wilmington Plant
Mills, Justin P	Senior Manager, Quality Assurance	Wilmington Plant
Mills, Lacey A	CS Order Management Specialist	Wilmington Plant
Mixon, John A	LEAD MANUFACTURING OPERATOR	Wilmington Plant
Molloy, Eric J	LEAD MANUFACTURING OPERATOR	Wilmington Plant
Monds, Michael C	WAREHOUSE OPERATOR	Wilmington Plant
Moore, Charles T	Associate Sys&NetworkEngr	Wilmington Plant
Moore, Kayla R	ANALYTICAL SCIENTIST	Wilmington Plant
Morgan, Lindsey H	SENIOR FINANCIAL ANALYST	REMOTE
Morris, Melissa G	QA SPECIALIST	Wilmington Plant
Morris, Rachel Michelle	SR QC CHEMIST	Wilmington Plant
Mosely, Troy A	SENIOR WAREHOUSE OPERATOR	Wilmington Plant
Nichols, Richard L	SENIOR MANUFACTURING OPERATOR	Wilmington Plant
Norton, Tracey L	Director CSC & Security	Wilmington Plant
Noyes, Shane A	OPERATIONS MANAGER	Wilmington Plant
O'Donnell, Meghan E	Security Technical Lead	Wilmington Plant
Osborne, James M	SENIOR PROCESS ENGINEER	Wilmington Plant
Osei, Kwame O	Staff Process Engineer	Wilmington Plant
Parsons, Benjamin E	MANUFACTURING OPERATOR	Wilmington Plant
Patel, Abhishek	Sr Engineer CQV	Wilmington Plant
Peroni, Jennifer	Sr Director Bus Devel, Sales & Marketing	REMOTE
Phillips, Frances R	Accounts Payable Coordinator	Wilmington Plant
Pierce, Andrew J	SR PROJECT ENGINEER	Wilmington Plant
Pierce, Connor M	QC COORDINATOR	Wilmington Plant
Pierce, Samantha L	Security Senior Officer	Wilmington Plant
Pizzo, Nicholas A	Manager Quality Control Systems	Wilmington Plant
Reagan, Patrick M	QC Stability Coordinator	Wilmington Plant
Ridgeway, Forrest J	MANUFACTURING OPERATOR	Wilmington Plant
Robinson, Jeffrey S	Maintenance & Engineering Scheduler	Wilmington Plant
Roman, Christopher	Senior Director Supply Chain	Wilmington Plant

Roslan, Katelyn E	SR QC CHEMIST	Wilmington Plant
Rossi, James A	Senior Wastewater Treatment Plant Operator	Wilmington Plant
Salerno, Brittany	QC LAB ANALYST	Wilmington Plant
Saltarelli, Michael	SENIOR MAINTENANCE TECHNICIAN	Wilmington Plant
Sasine, Joshua S	PROJECT MANAGER REGULATORY AFFAIRS	REMOTE
Schultz, Michael C	CFO Noramco	REMOTE
Scott, Garett D	PROGRAM MANAGER, NEW PRODUCT INTRO	REMOTE
Seynos, Yozabed Emanuel	CO-OP UNDERGRADUATE	Wilmington Plant
Sherwood, Jacqueline M	Security Senior Officer	Wilmington Plant
Shockley, Nicholas A	ASSOCIATE MANUFACTURING OPERATOR	Wilmington Plant
Simons, David N	SR. TECHNICAL SERVICES SPECIALIST	REMOTE
Simpson, Anthony	Senior Wastewater Treatment Plant Operator	Wilmington Plant
Sims, Taylor M	QC LAB ANALYST	Wilmington Plant
Smith, Adam Daniel	SENIOR MANUFACTURING OPERATOR	Wilmington Plant
Smith, Anthony Mark	SENIOR SUPERVISOR MAINTENANCE	Wilmington Plant
Smith, Robbie L	Sr Director Human Resources	Wilmington Plant
Smith, Troy W	WAREHOUSE OPERATOR	Wilmington Plant
Smyth, Matthew L	ASSOCIATE MANUFACTURING OPERATOR	Wilmington Plant
Snyder, Elizabeth	Sr Director Bus Devel, Sales & Marketing	REMOTE
Somers, John R	Senior Manager EHS	Wilmington Plant
Son, Sarak	SR QC LAB ANALYST	Wilmington Plant
South, Erika L	QC LAB ANALYST	Wilmington Plant
Stanley, Simuel L	EHS Engineer	Wilmington Plant
Stetser, Amanda M	QC LAB ANALYST	Wilmington Plant
Stevens, Garrett J	ASSOCIATE MANUFACTURING OPERATOR	Wilmington Plant
Stokes, Kelly P	MANUFACTURING SUPERVISOR	Wilmington Plant
Stritzinger, Ashlee A	QA SPECIALIST	Wilmington Plant
Stritzinger, Bailey E	ASSOCIATE MANUFACTURING OPERATOR	Wilmington Plant
Sullivan, Connor M	MANUFACTURING OPERATOR	Wilmington Plant
Sumner, Amanda P	Senior Manager Supply Chain	Wilmington Plant
Sun, Xianfeng	Director Process&Analytical R&D	Wilmington Plant
Swanson, Narra E	QC LAB ANALYST	Wilmington Plant
Taylor, Gary K	PROJECT MANAGER ENGINEERING	Wilmington Plant
Thompson, Marques S	MANUFACTURING OPERATOR	Wilmington Plant

Thompson, Steven C	ASSOCIATE MANUFACTURING OPERATOR	Wilmington Plant
Tolson, R Matthew	LEAD MANUFACTURING OPERATOR	Wilmington Plant
Turner, Mason A	PROGRAM MANAGER, NEW PRODUCT INTRO	REMOTE
Ung, Phyroun	SENIOR SUPERVISOR QUALITY ASSURANCE	Wilmington Plant
Vanaman, Alexandra	STAFF ENGINEER EHS	Wilmington Plant
Vecore, Michael J	Senior Supply Chain Specialist	Wilmington Plant
Waddington, Frank R	MANUFACTURING OPERATOR	Wilmington Plant
Walker, David J	MANUFACTURING OPERATOR	Wilmington Plant
Wang, Alina	CO-OP UNDERGRADUATE	Wilmington Plant
Ward, Matthew A	MANUFACTURING OPERATOR	Wilmington Plant
Washington, Albert R	MANUFACTURING OPERATOR	Wilmington Plant
Washington, Chassidy E	Security Lead	Wilmington Plant
Watkins, Anthony William	LEAD MANUFACTURING OPERATOR	Wilmington Plant
Watkins, Richard W	WAREHOUSE OPERATOR	Wilmington Plant
Watson, Paul A	MANUFACTURING OPERATOR	Wilmington Plant
White, Amanda Marie	Senior Customer Service Specialist	REMOTE
Whitfield, Robert L	Lead Wastewater Treatment Plant Operator	Wilmington Plant
Wollet, Corrine E	QC LAB ANALYST	Wilmington Plant
Wood, Joyce S	Associate Manager	REMOTE
Yu, Zhanqian	STAFF PROCESS SCIENTIST	Wilmington Plant
Zakian, Lindsey R	QC CHEMIST	Wilmington Plant
Zhong, Ping	SR ANALYTICAL SCIENTIST	Wilmington Plant
Ziegler, Andrew T	SR. QA SPECIALIST	Wilmington Plant

4AA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH03870	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10)

Section 1: General Information

Facility Name: Nuvalent, Inc.

Physical Address: One Broadway, 14th Floor, Schoenberg Suite

City: Cambridge State: MA Zip: 02142

Mailing Address (if different from physical address): One Broadway, 14th Floor

City: Cambridge State: Massachusetts Zip: 02142

Telephone: (857) 357-7000 Website: https://nuvalent.com

Name of Designated Representative (DR): Benjamin Lane

Licensing Company Email: statelicensing@nuvalent.com DR Email: blane@nuvalent.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical Products (medical devices, equipment, supplies, gases)	☐ Reverse Distributor
☐ Wholesalers		☐ Warehouse
☐ Veterinarians	☐ Others:	☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Distributors, Specialty Pharmacies		☒ Others: Virtual Manufacturer. See Description of Operations

Section 2: ONLY COMPLETE THIS SECTION IF THE COMPANY IS WHOLESALING [a]Medical Products (medical devices, equipment, supplies and gases). Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 3 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

Section 4: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): GlaxoSmithKline LLC

Corporation/Organization Name: Nuvalent, Inc.

Mailing Address: One Broadway, 14th Floor

City: Cambridge State: Massachusetts Zip: 02142

Telephone: (857) 357-7000 Email: statelicensing@nuvalent.com

Contact Person Name: Benjamin Lane

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	x	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 10: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale [a]Medical Products (medical devices, equipment, supplies, gases). (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Products (medical devices, equipment, supplies, gases), supply a copy of proof of insurance (NAC 639.6957).** The Medical Products wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 9)				
• **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20NRS%20639.500%20-%20Effective%2001.07.2026%20-%20Wholesaler%20-%20Post%20on%201.26.26.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Nuvalent, Inc.
Facility Name

Brian Vetter
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10-Aug-2026
Date

Board Use Only	Date Received: 8/17/26	Amount: $1000 ck 61160

From: edrls@fda.hhs.gov <edrls@fda.hhs.gov>
Sent: Monday, December 2, 2024 8:30 AM
To: Virginia Vetter <vvetter@nuvalent.com>
Subject: Labeler Code Request Approved

-------- External Email - Use Caution --------

---

eDRLS - Electronic Drug Registration & Listing System

Current Date: 02-DEC-2024
Labeler DUNS: 097816566
Labeler Name: Nuvalent, Inc.
Labeler Code Assigned: 85001

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**
For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

Nuvalent

DESCRIPTION OF OPERATIONS

Nuvalent, Inc. ("Nuvalent") is a Massachusetts based clinical-stage biopharmaceutical company focused on creating precisely targeted therapies for patients with cancer.
Nuvalent is a 100% wholly owned subsidiary of GlaxoSmithKline LLC.

Nuvalent Inc.'s products are manufactured by a Contract Manufacturer and will be distributed to Specialty Distributors, Specialty Pharmacies and Physicians' Offices by their Third-Party Logistics Provider, Integrated Commercialization Services, who is licensed to ship pharmaceutical products into your state.

CONTRACT MANUFACTURERS

We are using the following to produce our product:

CMO

Patheon, Inc.
2100 Syntex Court Mississauga, Ontario, Canada L5N 7K9
(365) 822-2803
FEIN: 3000264888

CPO

Sharp Packaging Services, LLC
7451 Keebler Way Allentown, PA 18106
(484) 866-0113
FEIN: 3004161147

THIRD-PARTY LOGISTICS

Integrated Commercialization Services
167 International Blvd, Suite A Brooks, KY 40109
Mike Lamb
(502) 955-5159

PRODUCT

As a virtual manufacturer, Nuvalent does not manufacture, distribute or store products at their Massachusetts facility. At no time do the contract manufacturers own Nuvalent's products, contract with Nuvalent's customers, invoice or sell Nuvalent products. Nuvalent's products are not controlled substances.

Labeler Code: 85001

Nuvalent's facility is 4,200 sq feet with hours of operation 9AM – 5PM EST Monday through Friday.

Nuvalent

Company Information

Nuvalent, Inc
One Broadway, 14th Floor, Schoenberg Suite Cambridge, MA 02142
Phone: (857) 357-7000
Email: statelicensing@nuvalent.com
Tax ID: 81-5112298

Ownership Information

Nuvalent, Inc. is 100% owned by GlaxoSmithKline LLC
410 Blackwell Street Durham NC 27701
Phone: (919) 368-0633
Email: brian.s.vetter@gsk.com
Tax ID: 23-1099050

Corporate Officers

Justin Huang, President and Secretary
1250 South Collegeville Rd, Mail Code UP4110 Collegeville, PA 19426
Phone: [redacted]

Kevin Ryan, Vice President and Treasurer
1250 S Collegeville Rd Collegeville, PA 19426
Phone: [redacted]

Brian Vetter, Vice President
410 Blackwell Street Durham NC 27701
Phone: [redacted]

Hatixhe Hoxha, Assistant Secretary
2929 Walnut Street Suite 1700 Philadelphia, PA 19104
Phone: [redacted]

The Commonwealth of Massachusetts

Secretary of the Commonwealth

State House, Boston, Massachusetts 02133

William Francis Galvin
Secretary of the
Commonwealth

Date: March 26, 2026

To Whom It May Concern :

I hereby certify that according to the records of this office,

NUVALENT, INC.

a corporation organized under the laws of

DELAWARE

on **January 25, 2017** was qualified to do business in this Commonwealth on

February 06, 2017 under the provisions of the General Laws, and I further certify that said corporation is still qualified to do business in this Commonwealth.

I also certify that said corporation is not delinquent in the filing of any annual reports required to date.

In testimony of which,
I have hereunto affixed the
Great Seal of the Commonwealth
on the date first above written.

William Francis Galvin

Secretary of the Commonwealth

Certificate Number: 26030629040

Verify this Certificate at: http://corp.sec.state.ma.us/CorpWeb/Certificates/Verify.aspx

Processed by: kma

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

Nuvalent, Inc.
One Broadway 14th Floor, Schoenberg Suite
Cambridge, MA 02142

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: VIR200114

Type: Virtual Manufacturer

Issue Date: 01/28/2026

Expiration Date: 03/31/2027

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 2369842

Application/License No. WH03870

Nuvalent, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is One Broadway, 14th Floor, Cambridge, MA 02142 (Address of Applicant/Principal), as PRINCIPAL, and Swiss Re Corporate Solutions America Insurance Corporation (Surety Company), a corporation organized under the laws of the state of Missouri (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1200 Main Street, Suite 800, Kansas City, MO 64105-2478 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on July 22, 2026 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 22nd day of July, 20 26.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

James R. Porter

SURETY

Surety Company's Representative

Donna M. Chiancone, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Angela Chen

Witness Sarah Park

SIGNED and SEALED in the presence of:

Witness Erica Higgins

Witness Karen A. Read

Countersigned by:

N/A
Nevada Resident Agent

SWISS RE CORPORATE SOLUTIONS

SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION ("SRCSAIC")
SWISS RE CORPORATE SOLUTIONS PREMIER INSURANCE CORPORATION ("SRCSPIC")

GENERAL POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, THAT SRCSAIC, a corporation duly organized and existing under laws of the State of Missouri, and having its principal office in the City of Kansas City, Missouri, and SRCSPIC, a corporation organized and existing under the laws of the State of Missouri and having its principal office in the City of Kansas City, Missouri, each does hereby make, constitute, and appoint:

DONNA M. CHIANCONE, TRAVIS W. SHAFFER, LORI N. BAYBUTT, KATHLEEN A. PETERSEN,

and LAURA A. RICKETT

JOINTLY OR SEVERALLY

Its true and lawful Attorney(s)-in-Fact to make, execute, seal and deliver, for and on its behalf and as its act and deed, bonds, consents of surety, or other writings obligatory in the nature of a bond on behalf of each of said Companies, as surety, on contracts of suretyship as are or may be required or permitted by law, regulation, contract or otherwise, provided that no bond or undertaking or contract or suretyship executed under this authority shall exceed the amount of:

TWO HUNDRED MILLION ($200,000,000.00) DOLLARS

This Power of Attorney is granted and is signed by facsimile under and by the authority of the following Resolutions adopted by the Boards of Directors of both SRCSAIC and SRCSPIC at meetings duly called and held on the 18th of November 2021:

"RESOLVED, that any two of the President, any Managing Director, any Senior Vice President, any Vice President, the Secretary or any Assistant Secretary be, and each or any of them hereby is, authorized to execute a Power of Attorney qualifying the attorney named in the given Power of Attorney to execute on behalf of the Corporation bonds, undertakings and all contracts of surety, and that each or any of them hereby is authorized to attest to the execution of any such Power of Attorney and to attach therein the seal of the Corporation; and it is

FURTHER RESOLVED, that the signature of such officers and the seal of the Corporation may be affixed to any such Power of Attorney or to any certificate relating thereto by facsimile, and any such Power of Attorney or certificate bearing such facsimile signatures or facsimile seal shall be binding upon the Corporation when so affixed and in the future with regard to any bond, undertaking or contract of surety to which it is attached."

SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION CORPORATE SEAL 1973 MISSOURI

By _____
David Satory, Senior Vice President of SRCSAIC & Senior Vice President of SRCSPIC

By _____
Gabriel Jacquez, Senior Vice President of SRCSAIC & Senior Vice President of SRCSPIC

SWISS RE CORPORATE SOLUTIONS PREMIER INSURANCE CORPORATION CORPORATE SEAL MISSOURI

IN WITNESS WHEREOF, SRCSAIC and SRCSPIC have caused their official seals to be hereunto affixed, and these presents to be signed by their authorized officers this 26th day of January, 2026.

Swiss Re Corporate Solutions America Insurance Corporation
Swiss Re Corporate Solutions Premier Insurance Corporation

State of Illinois
County of Cook ss

On this 26th day of January, 2026, before me, a Notary Public personally appeared David Satory, Senior Vice President of SRCSAIC and Senior Vice President of SRCSPIC, and Gabriel Jacquez, Senior Vice President of SRCSAIC and Senior Vice President of SRCSPIC, personally known to me, who being by me duly sworn, acknowledged that they signed the above Power of Attorney as officers of and acknowledged said instrument to be the voluntary act and deed of their respective companies.

OFFICIAL SEAL
KAREN M SZWEDA
Notary Public, State of Illinois
Commission No. 978628
My Commission Expires September 26, 2027

Karen M. Szweda, Notary

I, Jeffrey Goldberg, the duly elected Senior Vice President and Assistant Secretary of SRCSAIC and SRCSPIC, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney given by said SRCSAIC and SRCSPIC, which is still in full force and effect.

IN WITNESS WHEREOF, I have set my hand and affixed the seals of the Companies this 22nd day of July, 2026.

Jeffrey Goldberg, Senior Vice President &
Assistant Secretary of SRCSAIC & SRCSPIC

Swiss Re
Corporate Solutions
SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION

1450 American Lane, Suite 1100, SCHAUMBURG, ILLINOIS 60173
800/338-0753

SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION
A Missouri Corporation

BALANCE SHEET AS OF DECEMBER 31, 2025
(Statutory Basis)

Valuation of securities on National Association of Insurance Commissioner Basis

ASSETS		LIABILITIES	
Cash	496,907,141	Reserve for Unearned Premiums	283,797,146
Bonds	1,843,360,105	Reserve for Losses and Loss Adjustment Expenses	810,013,224
Common Stock	271,609,098	Funds Withheld	288,682,930
Other Invested Assets	0	Taxes and Other Liabilities	1,108,764,689
Other Admitted Assets	1,111,105,879	Surplus	1,231,724,234
TOTAL ADMITTED ASSETS	3,722,982,223	**TOTAL LIABILITIES & POLICYHOLDERS' SURPLUS**	3,722,982,223

The undersigned, being duly sworn, says: That he is Vice President of Swiss Re Corporate Solutions America Insurance Corporation, Kansas City, Missouri that said company is a corporation duly organized, existing by virtue of the Laws of the State of Missouri and that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress approved; July 1947 6 U.S.C. sec. 6-13; and that to the best of his knowledge and belief the above statement is a full, true and correct statement of the financial condition of the said Company on the 31st day of December, 2025.

Gabe Jacquez, Senior Vice President
Swiss Re Corporate Solutions America Insurance Corporation

Subscribed and sworn before me,
this 28th day of February, 2026.

Notary Public

OFFICIAL SEAL
KAREN M SZWEDA
Notary Public, State of Illinois
Commission No. 978628
My Commission Expires September 26, 2027

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Nuvalent, Inc.

Pharmacy/Wholesaler License # (if applicable) WH03870

Physical Address One Broadway, 14th Floor, Schoenberg Suite

City Cambridge State MA Zip 02142

Mailing Address (if different from physical address) One Broadway, 14th Floor

City Cambridge State Massachusetts Zip 02142

Telephone (857) 357-7000 Website https://nuvalent.com

Licensing Company Email statelicensing@nuvalent.com

Section 2: Personal Information

First Benjamin Middle Stephen Last Lane

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address One Broadway, 14th Floor

City Cambridge State Massachuse Zip 02142

Telephone [redacted] Email blane@nuvalent.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Texas A&M University		09/97 - 05/03	
Address	City	State	Zip
400 Bizzell St.	College Station	TX	77840
Diploma/Degree obtained, if any			
PH. D. Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Richard Stockton College		09/94 - 05/97	
Address	City	State	Zip
	Pomona	NJ	08240
Diploma/Degree obtained, if any			
B.S. Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Lacy Township High School		09/89 - 06/93	
Address	City	State	Zip
73 Haines St	Lanoka Harbor	NJ	08734
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2011 - Present	[redacted]	Lynnfield	MA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Nuvalent, Inc.			10/20 - Current
Business Address	**City**	**State**	**Zip**
One Broadway, 14th Floor, Schoenberg Suite	Cambridge	MA	02142
Phone	**Title**	**Number of Employed Hours**	
(857) 357-7000	Chief Technical Operations Officer	12,160	

Description of Duties

See Attached Resume

Business Name			From - To (MM/YY – MM/YY)
Agios Pharmaceuticals			09/14 - 10/20
Business Address	**City**	**State**	**Zip**
88 Sidney St.	Cambridge	MA	02139
Phone	**Title**	**Number of Employed Hours**	
(617) 649-8600	Sr. Director, Process Chemistry	11,680	

Description of Duties

See Attached Resume

Business Name			From - To (MM/YY – MM/YY)
Infinity Pharmaceuticals (No longer in business)			11/09 - 09/14
Business Address	**City**	**State**	**Zip**
1100 Massachusetts Ave. #4	Cambridge	MA	02138
Phone	**Title**	**Number of Employed Hours**	
(617) 453-1000	Associate Director, Process Chemistry	9,280	

Description of Duties

See Attached Resume

Business Name			From - To (MM/YY – MM/YY)
BIOGEN IDEC			01/05 - 10/09
Business Address	**City**	**State**	**Zip**
225 Binney St.	Cambridge	MA	02142
Phone	**Title**	**Number of Employed Hours**	
(781) 464-2000 / (617) 679-2000	Scientist II, Process Chemistry	9,440	

Description of Duties

See Attached Resume

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

BENJAMIN STEPHEN LANE

SUMMARY

Technical Operations functional lead with 17 years' experience in the pharmaceutical industry building teams to deliver on accelerated timelines

EXPERIENCE

NUVALENT, INC. — CAMBRIDGE, MA
One Broadway, 14th Floor 857-357-7000

Chief Technical Operations Officer — *2026-Present*
SVP, Technical Operations — 2022 – 2026
VP, Pharmaceutical Development — 2020 - 2022

- Oversight of Quality, CMC, and Supply Chain operations
- Member of the corporate leadership team

AGIOS PHARMACEUTICALS — CAMBRIDGE, MA
88 Sidney St 617-649-8600

Senior Director, Process Chemistry — 2014 – 2020

- Process Chemistry Department head overseeing a team of 9 people responsible for supporting everything from late-stage discovery to commercial manufacturing
  - Responsible for drug substance related activities including: salt form and/or polymorph selection, synthetic route selection/development, manufacturing, chemical engineering support, process validation, as well as regulatory strategy/dossier authoring
  - Augment outsourced research and manufacturing with internal research lab focused on preventing and solving scale-up and manufacturing challenges
- Supported taking 4 NCEs into clinical development in 4 years in addition to the commercialization of Tibsovo
- Mitapivat (i.e. AG-348, a Phase 3 program focused on treating anemia) Technical Operations asset-lead
  - Acting interface between Technical Operations and the Program Team ensuring that drug availability is not rate limiting and enabling on time NDA filing
  - Set the development strategy, timeline, and budget for all CMC related Mitapivat activities including drug substance, drug product, and analytical development
- Relationship manager for drug substance CROs and CMOs; conducting regular business review meetings to maximize productivity and quality
- Lead a collaboration with Legal to set IP strategies and gain freedom to operate

INFINITY PHARMACEUTICALS — CAMBRIDGE, MA
(No longer in Business)

Associate Director, Process Chemistry — 2009 – 2014

- Served as the drug substance lead for Infinity's flagship IPI-145 Phase III program, which became Duvelisib
- Lead a strong relationship with Regulatory CMC to support filings

  - Wrote drug substance sections for IND/IMPD filings for multiple clinical trials inside and outside oncology and prepared annual update reports
  - Drafted briefing packages for CMC focused FDA meetings
- Took an in licensed preclinical program from assimilation into our organization through an initial 6 kg GMP drug substance production in 5 months
  - Strategically set GMP starting material designation that was both accepted by regulatory agencies and accelerated pre-IND drug substance development
  - Refined drug substance isolation to deliver the desired polymorph, which was extended to a patent
- Developed a novel process that eliminated racemization, which was a bottleneck for manufacturing; shortened the production time from 4 weeks to 1.5 weeks for this step and increased the yield by 25%
- Discovered an alternative intermediate isolation that improved the diastereoselectivity in next step of a semisynthetic drug substance synthesis; increased production to support demanding clinical trial

BIOGEN IDEC CAMBRIDGE, MA
225 Binney Street 781-464-2000

Scientist II, Process Chemistry 2005 – 2009

- Lab Based process chemist responsible for early-phase process development and program transition into clinical development
- Designed synthesis that eliminated the need for a chiral prep-HPLC separation and produced a 15 kg cGMP batch to support initiation of Phase I studies within a year
- Developed new reduction conditions that shortened the synthesis of a regulatory starting material from 5 steps to 1, which also alleviated supply chain strain
- Developed a drug substance polymorph control strategy that was extended into a patent that prolonged IP coverage.
- Developed a new SNAr reaction without protecting groups that expanded our process IP space and, with other improvements, tripled the overall yield
- Set up Kilo-Lab with up to 50 L jacketed reactor systems and full data logging capabilities; made the first kilo-scale batches in internal lab
- Within 1 year, took an in-licensed program to 50 kg scale with improved process by:
  - Transferring technology from historical CMO to internal labs
  - Demonstrated improvements across 3 different steps that previously limited scale to 5 kg batches
  - Led transfer of improved process to a new CMO, which was eventually scaled to >100 kg per batch
- Identified impurities via independent synthesis based on mechanistic understanding and mass spec data; this was ahead of plan to isolate impurities by prep-HPLC

EDUCATION

TEXAS A&M UNIVERSITY COLLEGE STATION, TX
PH.D. CHEMISTRY 1997-2003
Advisor: Kevin Burgess
Dissertation: Metal Catalyzed Epoxidation Reactions with Hydrogen Peroxide

STOCKTON UNIVERSITY POMONA, NJ
B.S. CHEMISTRY 1994-1997

LACY TOWNSHIP HIGH SCHOOL LANOKA HARBOR, NJ
HIGH SCHOOL DIPLOMA 1989-1993

PUBLICATIONS

1. Fandrick, Daniel R.; Grenier, Louis; Lane, Benjamin S.; Lee, Jaemoon; Leung, Cheuk-Yui; Li, Hui; Mellott, Karlie E.; Simone, Eric; Sizemore, Jacob P. *Crystalline salts or amorphous forms of 2-((1h-pyrazol-3-yl)methyl)-6-((6-aminopyridin-2-yl)methyl)-4-methyl-4,6-dihydro -5h-thiazolo[5',4':4,5]pyrrolo[2,3-d]pyridazin-5-one.* PCT Int. Appl. (2024). WO2024238659 A1

2. Cooper, Christopher G. F.; Gerard, Baudouin; Horan, Joshua Courtney; Kropp, Jason T.; Lane, Benjamin Stephen; Pearson, David James; Maceachern, Lauren Ashley; He, Yameng; Singh, Mandeep; Narayanappa, Arkesh. *Solid forms, pharmaceutical compositions and preparation of heteroaromatic macrocyclic ether compounds.* PCT Int. Appl. (2023), WO2023196900 A1

3. Chen, Sibao; Cooper G. F., Christopher; Gerard, Baudouin; Horan, Joshua Courtney; Kropp, Jason T.; Lane, Benjamin Stephen; Pearson, David James. *Solid forms, pharmaceutical compositions and preparation of heteroaromatic macrocyclic ether compounds.* PCT Int. Appl. (2023), WO2023056405 A1

4. Rios Lizarraga, Jose Luis; Depew, Kristopher; Grenier, Louis; Lane, Benjamin S.; Simone, Eric; Sizemore, Jacob Paul. *Preparation of solid state forms of 3-(cyclohex-1-en-1-yl)-6-(4-methoxyphenyl)-2-phenyl-5-(pyridin-2-ylamino)pyrazolo[1,5-a]pyrimidin-7(4H)-one.* PCT Int. Appl. (2022), WO2021-US45656

5. Rios Lizarraga, Jose Luis; Depew, Kristopher; Grenier, Louis; Lane, Benjamin S.; Simone, Eric; Sizemore, Jacob Paul. *Preparation of solid state forms of 3-(cyclohex-1-en-1-yl)-6-(4-methoxyphenyl)-2-phenyl-5- (pyridin-2-ylamino)pyrazolo[1,5-a]pyrimidin-7(4H)-one.* PCT Int. Appl. (2021), WO2021-US45656

6. Zhu, Ruiheng; Reddy, Ramesh; Ding, Man; Xu, Ming; Deng, Chaoyi; Tadayon, Sam; Li, Hui ; Depew, Kristopher; Lane, Benjamin. *Development and Scale-Up of a Continuous Manufacturing Process for a Hydrazine Condensation Reaction.* Organic Process Research & Development. **2021**, 25, 199-205.

7. Lane, Benjamin S.; Gu, Chong-Hui. *Preparation of trifluropropanyltriazine compound, cocrystals and pharmaceutical compositions thereof for treating cancer.* PCT Int. Appl. (2019), WO 2019090059 A1 20190509.

8. Austad, Brian C.; Hague, Andrew B.; White, Priscilla; Peluso, Stephane; Nair, Somarajan J.; Depew, Kristopher M.; Grogan, Michael J.; Charette, Andre B.; Yu, Lin-Chen; Lory, Caroline D.; Grenier, Louis; Lescarbeau, Andre; Lane, Benjamin S.; Lombardy, Richard; Behnke, Mark L.; Koney, Nii; Porter, James R.; Campbell, Matthew J.; Shaffer, Jeanne; Xiong, Jimin; Helble, Joseph C.; Foley, Michael A.; Adams, Julian; Castro, Alfredo C.; Tremblay, Martin R. *Development of a Multi Kilogram-Scale, Tandem Cyclopropanation Ring-Expansion Reaction en Route to Hedgehog Antagonist IPI-926.* Organic Process Research & Development. **2016**, 20, 786-798.

9. Ren, Pingda; Martin, Michael; Isbester, Paul; Lane, Benjamin S.; Kropp, Jason. *Processes for preparing isoquinolinones and solid forms of isoquinolinones.* PCT Int. Appl. (2012), WO 2012097000 A1 20120719.

10. Guckian, Kevin; Carter, Mary Beth; Lin, Edward Yin-Shiang; Choi, Michael; Sun, Lihong; Boriack-Sjodin, P. Ann; Chuaqui, Claudio; Lane, Benjamin; Cheung, Kam; Ling, Leona; et al. *Pyrazolone based TGFbR1 kinase inhibitors.* Bioorganic & Medicinal Chemistry Letters. **2010**, 20, 326-329.

11. Guan, B.; Ishchenko, A.; Chen, W,; Cossrow, J.; Franklin, L.; Guan, B.; Jones, H.; Kumaravel, G,; Lane, B.; Littke, A.; Lugovskoy, A.; Peng, H.; Powell, N.; Raimundo, B.; Tanaka, H.; Vessels, J.; Wynn, T.; Xin, Z. *Pyrimidine-4-carboxamide compounds useful as Raf kinase inhibitors and their preparation and use in the treatment of Raf-mediated diseases.* PCT Int. Appl. (2009). WO 2009006389 A2 20090108.

12. Janicki, S.; Chang, H.; Chen, W.; Kiesman, W.; Lane, B.; Todd, B. *Polymorphs and solvates of a pharmaceutical and methods of making.* PCT Int. Appl. (2008), WO 2008086201 A1 20080717.

13. Chang, H; Lane, B. S.; Chen, W.; Janicki, S.; Todd, R.; Kiesman, W. *Preparation of [1,2,3,]triazolo[4,5-d]pyrimidine compounds as purine receptor antagonists.* PCT Int. Appl. (2008), WO 2008088927 A1 20080724.

14. Toure, B. B.; Lane, B. S.; Sames, D.. Direct C-H Bond Arylation: Catalytic C-H Arylation of SEM-Protected Azoles

with Palladium Complexes of NHCs and Phosphines. Organic Letters. **2006**, 8, 1979-1982.

15. Wang, X.; Lane, B. S.; Sames, D., Direct C-Arylation of Free (NH)-Indoles and Pyrroles Catalyzed by Ar- Rh(III) Complexes Assembled In Situ. J. Am. Chem. Soc. **2005**, 127, 4996-4997.
16. Lane, B. S.; Brown, M. A.; Sames, D., Direct Palladium-Catalyzed C-2 and C-3 Arylation of Indoles: A Mechanistic Rationale for Regioselectivity. J. Am. Chem. Soc. **2005**, 127, **8050-8057**.
17. Lane, B. S.; Sames, D., Direct C-H Bond Arylation: Selective Palladium Catalyzed C2-Arylation of N-Substituted Indoles. Organic Letters. **2004**, 6, **2897-900**.
18. Gao, M. Z.; Gao, J.; Lane, B. S.; Zingaro, R. A., *An Amino Acid Co-catalyzed Asymmetric Aldol Reaction*. Chemistry Letters. **2003**, 32, 524-25.
19. Lane, B. S., Metal Catalyzed Epoxidation Reactions with Hydrogen Peroxide. Dissertation. **2003**, Texas A & M University.
20. Lane, B. S.; Burgess, K., Metal-Catalyzed Epoxidations of Alkenes with Hydrogen Peroxide. Chem. Rev. **2003**, 103, 2457-74.
21. Lane, B. S.; Vogt, M.; DeRose, V. J.; Burgess, K., *Manganese Catalyzed Epoxidations of Alkenes in Bicarbonate Solutions*. J. Am. Chem. Soc. **2002**, 124, 11947-54.
22. Lane, B. S.; Burgess, K., A Cheap, Catalytic, Scalable, and Environmentally Benign Method for Alkene Epoxidations. J. Am. Chem. Soc. **2001**, 123, 2933-4

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I, Benjamin Lane, **certify that as the designated representative for**

Nuvalent, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Benjamin Lane

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07 AUG 2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Benjamin Lane

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07 AUG 2026

Date

Please have this section completed in the presence of a Notary Public.

State of MASSACHUSETTS, ss. County of ESSEX

I, Benjamin Lane, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

07 AUG 2026

Date

Subscribed and Sworn to before me this 7th day of AUGUST.

Notary Public Signature

LETHYCIA VILLANUEVA
MY COMMISSION EXPIRES FEBRUARY 19, 2032
NOTARY PUBLIC
COMMONWEALTH OF MASSACHUSETTS

(Seal)

Nuvalent, Inc. List of Employees
Cambridge One Broadway Home Office as of 07.15.2026

Last Name	First Name
Adams	Ruth
Andrews	Kristin
Balcom	Alexandra
Belinsky	Lauren
Bertonazzi	Kristen
Bowlin	Holly
Brabant	Adelicia
Byrnes	Kristi
Campbell	Matthew
Carnase	Kyle
Carter	Bennett
Chaudhari	Smruti
Chen	Angela
Chubet	Paula
Concannon	Amanda
Crabtree	Leah
Critchley	Stephen
Cuff	Megan
Dardeno	Michelle
Desai	Kuldeep
Diesso	Richard
Dillon	Tamara
Dong Si	Tuan
Dumas	Cameron
Ellis	Karen
Estrada	Brianna
Fan	Zi Peng
Faretra	Joya
Flaherty	Erin
Gerard	Baudouin
Gilley	Ellen
Goluboff	Denise
Granfield	Christine
Gu	Franklin

Last Name	First Name
Hanson	Bethany
Hapgood	Megan
Hebert	Solange
Horan	Joshua
Kantcheva	Aneta
Kehrig	Kristina
Kennedy	Ashton
Kilroy	Tallulah
Kropp	Jason
Kulkarni	Shashank
Lane	Benjamin
Le	Lidya
LeDoux	Juli
Lei	Jacky
Ma	Julie
Magnan	Allison
Maiola	Morgan
Margossian	Steve
Martin	Christian
McCabe	Riley
McConarty	Nathan
Mente	Scot
Mitchell	Caitlyn
Morelli	Lisa
Nechay	Misha
Nguyen	Tuan
Noci	Darlene
Noe	Rachel
Park	Sarah
Patel	Meghavi
Patel	Utsav
Pelish	Henry
Pileeki	Sarah
Porter	James
Powers	Paige
Prytko	Robert
Ray	Debarpita

Last Name	First Name
Riley	Malgorzata
Rothwell	Paula
Samant	Manoj
Schneeberg	Christine
Secord	Linda
Shen	Junwu
Shou	Xiaohong
Silva	Kelly
Smith	Gregory
Soglia	John
Staffin	Kevin
Sun	Yuting
Tangpeerachaikul	Anupong
Turner	Christopher
Vaze	Onkar
Vienneau	Brenda
Walsh	Michael
White	Scott
Williams	Brett
Wilson	Lindsey
Youn	Roy
Zeoli	Samantha
Zhao	Wanying
Zhu	Viola

4BB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Ortho Organizers, Inc.

Physical Address: 800 King George Blvd., Suite 100

City: Savannah State: GA Zip: 31419

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 760-448-8600 Website: https://henryscheinortho.com/

Name of Designated Representative (DR): Burrell, Nathanael Zeb Lee

Licensing Company Email: diorthorahso@henryschein.com DR Email: Zeb.Burrell@henryschein.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	■ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Relabeler

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10/15/2025
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year. This applies to orthodontic medical devices, not pharmaceutical products.

Name: Ultimate Wireforms, Inc.
Address: 200 Central Street City: Bristol State: CT Zip: 06010

Name: Kent Elastomer Products, Inc.
Address: 1500 St. Clair Ave. City: Kent State: OH Zip: 44240

Name: CDB Corporation
Address: 8770 Trade Street NE City: Leland State: NC Zip: 28451

Name: Hu-Friedy Mfg. Co., LLC
Address: 3232 N. Rockwell St. City: Chicago State: IL Zip: 60618

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California / Secretary of State
Parent Company (if any): Ortho Organizers Holdings, Inc.
Corporation/Organization Name: Ortho Organizers, Inc.
Mailing Address: 800 King George Blvd., Suite 100
City: Savannah State: GA Zip: 31419
Telephone: 760-448-8600 Email: dlorthorahso@henryschein.com
Contact Person Name: Thomas Arnold

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Ortho Organizers, Inc.

Facility Name

Thomas Arnold

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/15/2025

Date

Board Use Only	Date Received: 10170725	Amount: $1000.00

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
ORTHO ORGANIZERS, INC.
Business Trade Name:
Henry Schein Orthodontics

800 King George Blvd, Suite 100
Savannah, GA 31419
Registration Number: 2081322
FEI Number*: 2081322
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2026

Owner/Operator:
ORTHO ORGANIZERS , INC.[6]
800 King George Blvd, Suite 100
Savannah, GA US 31419
Owner/Operator Number: 2081322[7]

Official Correspondent:
Nicole Rajek
800 King George Blvd, Suite 100
Savannah, GA 31419
Phone: 1-262-7055492

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

---

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2081322&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2081322&OwnerOperator

Page Last Updated: 12/01/2025

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsc | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of **Health & Human Services**

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2081322&OwnerOperator

Name: Ortho Organizers, Inc.
Address of Location: 800 King George Blvd., Suite 100, Savannah, GA 31419

Corporate Officers as of October 2025

Name: Zachary Meli
Title: President
Address: [redacted] Ramsey, NJ 07446
E-mail: zachary.meli@henryschein.com
Phone: [redacted]

Name: Ronald N. South
Title: SVP-Chief Financial Officer
Address: [redacted] Melville, NY 11747
E-mail: Ronald.South@henryschein.com
Phone: [redacted]

Name: Laura Jadezuk
Title: Vice President, Global Tax
Address: [redacted] Melville, NY 11747
E-mail: laura.jadezuk@henryschein.com
Phone: [redacted]

Name: Michael Amodio
Title: Treasurer
Address: [redacted] Melville, NY 11747
E-mail: Michael.amodio@henryschein.com
Phone: [redacted]

Name: Michael S. Ettinger
Title: Executive Vice President
Address: [redacted] Melville, NY 11747
E-mail: michael.ettinger@henryschein.com
Phone: [redacted]

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	ORTHO ORGANIZERS, INC.
Entity No.:	1046418
Registration Date:	06/11/1981
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of January 09, 2026.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 407773938

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

Ortho Organizers, Inc.
Ownership Structure



STATE OF GEORGIA
Georgia Board of Pharmacy
Manufacturing Pharmacy
LICENSE NO. PHMA000659 Status: Active

Ortho Organizers Inc
Henry Schein Orthodontics
800 King George Blvd
Ste 100
Savannah GA 31419

Expires: 06/30/2027
Issued: 11/26/2025

Real-time license verification is available at gadch.mylicense.com/verification

Above is your wall certificate license to practice as a **Manufacturing Pharmacy** in the State of Georgia. A pocket-sized license card is below.

Please make note of the expiration date on your license. It is your responsibility to renew your license before it expires.
Please notify the Board if you have a change of address.

STATE OF GEORGIA
Georgia Board of Pharmacy
Manufacturing Pharmacy
LICENSE NO. PHMA000659 Status: Active
Ortho Organizers Inc
800 King George Blvd
Ste 100
Savannah GA 31419

Expires: 06/30/2027
Issued: 11/26/2025
Real-time license verification is available at gadch.mylicense.com/verification

STATE OF GEORGIA
Georgia Board of Pharmacy
Wholesaler Pharmacy
LICENSE NO. PHWH006152 Status: Active

Ortho Organizers Inc
Henry Schein Orthodontics
800 King George Blvd
Ste 100
Savannah GA 31419

Expires: 06/30/2027
Issued: 11/26/2025

Real-time license verification is available at gadch.mylicense.com/verification

Above is your wall certificate license to practice as a **Wholesaler Pharmacy** in the State of Georgia. A pocket-sized license card is below.

Please make note of the expiration date on your license. It is your responsibility to renew your license before it expires.
Please notify the Board if you have a change of address.

STATE OF GEORGIA
Georgia Board of Pharmacy
Wholesaler Pharmacy
LICENSE NO. PHWH006152 Status: Active
Ortho Organizers Inc
800 King George Blvd
Ste 100
Savannah GA 31419

Expires: 06/30/2027
Issued: 11/26/2025
Real-time license verification is available at gadch.mylicense.com/verification

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 07/15/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Aon Risk Services Northeast, Inc.
New York NY Office
One Liberty Plaza
165 Broadway, Suite 3201
New York NY 10006 USA

CONTACT NAME:
PHONE (A/C. No. Ext): (866) 283-7122 **FAX (A/C. No.):** (800) 363-0105
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Berkshire Hathaway Specialty Ins Company	22276
INSURER B:	QBE Specialty Insurance Company	11515
INSURER C:	ProAssurance Specialty Insurance Company	17400
INSURER D:	Liberty Mutual Fire Ins Co	23035
INSURER E:		
INSURER F:		

INSURED
Henry Schein, Inc.,
Subsidiaries & Affiliates
135 Duryea Road
Melville NY 11747 USA

COVERAGES **CERTIFICATE NUMBER:** 570114429750 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
D	X COMMERCIAL GENERAL LIABILITY			TB26210933630 35	06/01/2025	06/01/2026	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$100,000
							MED EXP (Any one person)	$5,000
							PERSONAL & ADV INJURY	$1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$2,000,000
	POLICY PRO-JECT X LOC						PRODUCTS - COMP/OP AGG	Excluded
	OTHER							
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	
	ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						PER STATUTE OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N/A						E.L. EACH ACCIDENT	
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	
							E.L. DISEASE-POLICY LIMIT	
C	Products Liability			N25NY380022 Claims Made	06/01/2025	06/01/2026	Each Occurrence Aggregate	$2,000,000 $2,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Emergo Global Consulting LLC is included as additional insured in accordance with the provisions of the General Liability and Products Liability policies.

CERTIFICATE HOLDER

Emergo Global Consulting LLC
and its subsidiaries
2500 Bee Cave Road
Building 1, Suite 300
Austin TX 78746 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast, Inc.

Holder Identifier :

Certificate No : 570114429750

©1988-2015 ACORD CORPORATION. All rights reserved.

AGENCY CUSTOMER ID: 570000025511
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Henry Schein, Inc.,
POLICY NUMBER: See Certificate Number: 570114429750	
CARRIER: See Certificate Number: 570114429750 / NAIC CODE	EFFECTIVE DATE

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 FORM TITLE: Certificate of Liability Insurance

Named Insureds

Ace Southern Surgical Solutions
Ace Surgical Supply Company, Inc.
AEP MPE Holdings, LLC
All Star Orthodontics
BIOHORIZONS IMPLANT SYSTEMS, INC.
Camlog
CB Healthcare Consulting GmbH
Cleanpac Inc
DenMat Holdings, LLC
Dental Instrument Sales & Service, LLC
Dental Practice Transitions
Dentrix Dental Systems
eAssist Inc.
eAssist Publishing LLC
Edge Endo
Exan Enterprises
Firefly Supply LLC
G.I.V. Inc.
General Injectibles & Vaccines, Inc.
Hand Piece Parts & Repair, Inc.
Hayes Handpiece Franchises, Inc.
HealthFirst
Henry Schein, Inc
Henry Schein and Schvadent
Henry Schein Dental, Inc.
Henry Schein Global Sourcing, Inc.
Henry Schein Medical
Henry Schein MSO, LLC
Henry Schein One, LLC
Henry Schein Practice Solutions
Henry Schein Services GmbH
Henry Schein, Supply
HF Acquisition Co. LLC
HSG-S Corp
Impromed, LLC.
Insource, Inc.
Lighthouse 360, Inc.
Midway Dental Supply LLC
My Care Supplies, LLC
NAR Medical Depot LLC
NAR Training LLC
North American Rescue LLC and TQM, LLC
ORTHO2 LLC
Ortho Organizers, Inc.
Ortho Technology, Inc.
Precision One Medical Inc.
Prism Medical Products
RXWORKS, INC.
Sesame Communications
Southern Anesthesia & Surgical Inc.
Shield HealthCare
TDSC, Inc.
The Custom Milling Center, Inc.
US Endodontics
Vulcan Custom Dental
Zahn Dental Company, Inc.
Zahn/Darby Lab

© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 015228782

Application/License No. _____

ORTHO ORGANIZERS, INC. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 800 King George Blvd., Suite 100 Savannah, GA 31419 (Address of Applicant/Principal), as PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of MA (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on September 30, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 30th day of September, 20 25.

APPLICANT/PRINCIPAL
ORTHO ORGANIZERS, INC.

Authorized Representative

SURETY COMPANY
LIBERTY MUTUAL INSURANCE COMPANY

Surety Company's Representative

Sandra Diaz, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Anne Potter

Witness Frances Rodriguez

Countersigned by:

Nevada Resident Agent
Aklima Noorhassan,
NV Non-Resident Agent License No. 3163993

Posted February 20, 2020

Liberty Mutual. SURETY

POWER OF ATTORNEY

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8213584-015009

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Aklima Noorhassan; Anne Potter; Beverly A. Woolford; Debra A. Deming; Frances Rodriguez; Francesca Kazmierczak; Jennifer L. Jakaitis; Pablo Garcia Horcajo; Peter Healy; Sandra Diaz; Susan A. Welsh; Valorie Spates; Vilma Gonzalez

all of the city of New York state of NY each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 2nd day of April, 2025.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 2nd day of April, 2025 before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2029
Commission number 1128044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 30th day of September, 2025.

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02/24

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Liberty Mutual. SURETY

LIBERTY MUTUAL INSURANCE COMPANY

FINANCIAL STATEMENT – DECEMBER 31, 2024

Assets		Liabilities	
Cash and Bank Deposits	$4,608,826,756.00	Unearned Premiums	$9,890,896,878.00
*Bonds – U.S Government	$4,281,375,446.74	Reserve for Claims and Claims Expense	$29,467,071,865.00
*Other Bonds	$21,566,489,527.26	Funds Held Under Reinsurance Treaties	$341,948,172.00
*Stocks	$15,589,644,012.00	Reserve for Dividends to Policyholders	$954,025.00
Real Estate	$86,497,925.00	Additional Statutory Reserve	$150,547,865.00
Agents' Balances or Uncollected Premiums	$7,512,975,129.00	Reserve for Commissions, Taxes and Other Liabilities	$5,049,906,410.00
Accrued Interest and Rents	$225,249,712.00	**Total**	**$47,104,416,171.00**
Other Admitted Assets	$19,367,663,200.00	Special Surplus Funds	$174,153,086.00
		Capital Stock	$10,000,075.00
		Paid in Surplus	$13,209,595,772.00
		Unassigned Surplus	$13,415,980,561.00
		Surplus to Policyholders	$27,435,067,490.00
Total Admitted Assets	**$74,539,483,661.00**	**Total Liabilities and Surplus**	**$74,539,483,661.00**

* Bonds are stated at amortized or investment value; Stocks at Association Market Values.
The foregoing financial information is taken from Liberty Mutual Insurance Company's financial statement filed with the Massachusetts Department of Insurance.

I, TIM MIKOLAJEWSKI, Assistant Secretary of Liberty Mutual Insurance Company, do hereby certify that the foregoing is a true, and correct statement of the Assets and Liabilities of said Corporation, as of December 31, 2024, to the best of my knowledge and belief.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation at Seattle, Washington, this 8th day of March, 2025.

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

Timothy A. Mikolajewski

Timothy A. Mikolajewski, Assistant Secretary

LMS-1262/LMIC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Ortho Organizers, Inc. MDEG License # (if applicable): _____

Physical Address: 800 King George Blvd., Suite 100

City: Savannah State: GA Zip: 31419

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 760-448-8600 Website: https://henryscheinortho.com/

Licensing Company Email: dlorthorahso@henryschein.com

Section 2: Personal Information

First: Nathanael Middle: Zeb Lee Last: Burrell

Alias(es, nicknames, name changes, etc.): Zeb

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Pooler State: GA Zip: [redacted]

Telephon[redacted] Email: Zeb.Burrell@HenrySchein.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Pinewood Christian Academy		01/06 - 01/10	
Address	**City**	**State**	**Zip**
1 N Henry St	Claxton	GA	30417
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/18 - Current	[redacted]	Pooler	GA	[redacted]
01/15 - 06/18		Bloomingdale	GA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Ortho Organizers, Inc.			11/25 - Current	
Business Address		**City**	**State**	**Zip**
800 King George Blvd., Suite 100		Savannah	GA	31419
Phone	**Title**		**Number of Employed Hours**	
912-925-8525	Quality Control Supervisor		160	

Description of Duties

Planning and assigning daily tasks, ensure compliance with local, state and federal laws, training employees, and implementing continuous improvements initiatives to enhance efficiency with online orders.

Business Name			From - To (MM/YY – MM/YY)	
Brasseler USA			07/25 - Current	
Business Address		**City**	**State**	**Zip**
1 Brasseler Blvd		Savannah	GA	31419
Phone	**Title**		**Number of Employed Hours**	
912-925-8525	Quality Control Supervisor		384	

Description of Duties

Work alongside a team of inspectors and manage Quality Control to ensure Quality product moves forward.

Business Name			From - To (MM/YY – MM/YY)	
Brasseler USA			12/21 - 07/25	
Business Address		**City**	**State**	**Zip**
1 Brasseler Blvd		Savannah	GA	31419
Phone	**Title**		**Number of Employed Hours**	
912-925-8525	Quality Engineering Technician		7360	

Description of Duties

Worked closely with Engineering and Production on various projects including NPI, Risk, EUMDR submission, Calibration, Reporting, Customer Complaints.

Business Name			From - To (MM/YY – MM/YY)	
Brasseler USA			01/19 - 12/21	
Business Address		**City**	**State**	**Zip**
1 Brasseler Blvd		Savannah	GA	31419
Phone	**Title**		**Number of Employed Hours**	
912-925-8525	Quality Assurance Inspector		6088	

Description of Duties

Conducted inspections of Receiving, Production, and Packaging products to ensure conformity to specifications.

Business Name			From - To (MM/YY – MM/YY)	
Brasseler USA			08/14 - 01/19	
Business Address		**City**	**State**	**Zip**
1 Brasseler Blvd		Savannah	GA	31419
Phone	**Title**		**Number of Employed Hours**	
912-925-8525	Machine Operator		9232	

Description of Duties

Operated and maintained multiple machines to produce finished product from material and perform in process checks to ensure conformity.

Continue on next page if additional space is needed.

Signed by:
Zeb Burrell
12/19/2025
Signer Name: Zeb Burrell
Signing Reason: I approve this document
Signing Time: 12/19/2025 | 1:11:59 PM PST
D3943A65E46241009B53D1D673C2E6B8

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Signed by:
Zeb Burrell 12/19/2025
Signer Name: Zeb Burrell
Signing Reason: I approve this document
Signing Time: 12/19/2025 | 1:12:07 PM PST
D3943A65E46241009B53D1D673C2E6B8

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Nathanael Burell
Original Signature (electronic, copies or stamps not accepted)

10/08/2025
Date

I, Nathanael Burrell, **certify that as the MDEG Administrator for**

Ortho Organizers, Inc.,

that I (initial that you have read and meet the following requirements):

1. ZB Have a high school diploma or its equivalent;
2. ZB Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ZB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ZB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nathanael Burrell
Print Name (First, Last)

Nathanael Burrell
Original Signature (electronic, copies or stamps not accepted)

10/08/2025
Date

Board Use Only	Date Received: 10/20/25

9/9/2026

To:

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway
Suite 206
Reno, NV 89521

RE: Statement regarding residency as it applies to Designated Representative application for Ortho Organizers, Inc.

To Whom It May Concern:

I, Brent Couey, am physically present at Ortho Organizers, Inc. in Savannah during daily operations on weekdays. My personal address is in Tennessee, where I reside during the weekends. My permanent, official full-time residence, will be in Savannah, GA within 2 weeks of this signed letter.

Sincerely,

Signed by:
BrentCouey
Signer Name: BrentCouey
Signing Reason: I approve this document
Signing Time: 9/10/2026 | 10:32:58 AM PDT
8C5AEAD2C0A24804AD0FED1223263C32

Brent Couey
9/10/2026
Director, Quality Assurance

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Ortho Organizers, Inc.
Pharmacy/Wholesaler License # (if applicable):
Physical Address: 800 King George Blvd., Suite 100
City: Savannah State: GA Zip: 31419
Mailing Address (if different from physical address):
City: State: Zip:
Telephone: 760-448-8600 Website: https://henryscheinortho.com/
Licensing Company Email: dlorthorahso@henryschein.com

Section 2: Personal Information

First: Nathanael Middle: Zeb Lee Last: Burrell
Alias(es, nicknames, name changes, etc.): Zeb
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X
Mailing Address: [redacted]
City: Pooler State: GA Zip: [redacted]
Telephone: [redacted] Email: Zeb.Burrell@HenrySchein.com
Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Pinewood Christian Academy		01/06 - 01/10	
Address	**City**	**State**	**Zip**
1 N Henry St	Claxton	GA	30417
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06-18 - Current	[redacted]	Pooler	GA	[redacted]
01/15 - 06/18		Bloomingdale	GA	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Ortho Organizers, Inc.			11/25 - Current
Business Address	**City**	**State**	**Zip**
800 King George Blvd., Suite 100	Savannah	GA	31419
Phone	**Title**	**Number of Employed Hours**	
912-925-8525	Quality Control Supervisor	160	

Description of Duties

Planning and assigning daily tasks, ensure compliance with local, state and federal laws, training employees, and implementing continuous improvements initiatives to enhance efficiency with online orders.

Business Name			From - To (MM/YY – MM/YY)
Brasseler USA			07/25 - Current
Business Address	**City**	**State**	**Zip**
1 Brasseler Blvd	Savannah	GA	31419
Phone	**Title**	**Number of Employed Hours**	
912-925-8525	Quality Control Supervisor	384	

Description of Duties

Work alongside a team of inspectors and manage Quality Control to ensure Quality product moves forward.

Business Name			From - To (MM/YY – MM/YY)
Brasseler USA			12/21 - 07/25
Business Address	**City**	**State**	**Zip**
1 Brasseler Blvd	Savannah	GA	31419
Phone	**Title**	**Number of Employed Hours**	
912-925-8525	Quality Engineering Technician	7360	

Description of Duties

Worked closely with Engineering and Production on various projects including NPI, Risk, EUMDR submission, Calibration, Reporting, Customer Complaints.

Business Name			From - To (MM/YY – MM/YY)
Brasseler USA			01/19 - 12/21
Business Address	**City**	**State**	**Zip**
1 Brasseler Blvd	Savannah	GA	31419
Phone	**Title**	**Number of Employed Hours**	
912-925-8525	Quality Assurance Inspector	6088	

Description of Duties

Conducted inspections of Receiving, Production, and Packaging products to ensure conformity to specifications.

Business Name			From - To (MM/YY – MM/YY)
Brasseler USA			08/14 - 01/19
Business Address	**City**	**State**	**Zip**
1 Brasseler Blvd	Savannah	GA	31419
Phone	**Title**	**Number of Employed Hours**	
912-925-8525	Machine Operator	9232	

Description of Duties

Operated and maintained multiple machines to produce finished product from material and perform in process checks to ensure conformity.

Continue on next page if additional space is needed.

Signed by: Zeb Burrell 12/19/2025

Signer Name: Zeb Burrell
Signing Reason: I approve this document
Signing Time: 12/19/2025 | 1:12:16 PM PST
D3943A65E46241009B53D1D673C2E6B8

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Signed by:
Zeb Burrell
12/19/2025
Signer Name: Zeb Burrell
Signing Reason: I have reviewed this document
Signing Time: 12/19/2025 | 1:12:27 PM PST
D3943A65E46241009B53D1D673C2E6B8

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Nathanael Burrell
Original Signature (electronic, copies or stamps not accepted)

10/08/2025
Date

I, Nathanael Burrell, **certify that as the designated representative for**

Ortho Organizers, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ZB I am at least 21 years of age;
3. ZB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ZB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ZB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ZB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ZB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Nathanael Burrell

Print Name (First, Last)

Nathanael Burrell

Original Signature (electronic, copies or stamps not accepted)

10/08/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nathanael Burrell

Print Name (First, Last)

Nathanael Burrell — 10/08/2025

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Georgia, ss. County of Chatham

I, Nathanael Burrell, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Nathanael Burrell — 10/08/2025

Original Signature — **Date**

Subscribed and Sworn to before me this 8th day of October 2025

Pamela Marie Kennedy

Notary Public Signature

OFFICIAL SEAL
PAMELA MARIE KENNEDY
NOTARY PUBLIC-GEORGIA
CHATHAM COUNTY
My Comm. Expires Feb. 19, 2028

(Seal)

Worker	Job Title	Business Unit	Division	Manager
Kimberly Rogert (On Leave)	Sr Manager, Finance - HSG	Henry Schein Products Group	Orthodontics Group	Adolfo Alvarado
Mark Chaconas	Sr Manager, Operations Finance - Orthodontics	Henry Schein Products Group	Orthodontics Group	Adolfo Alvarado
Christophor Simeno	QAD Data Analyst - Ortho	Henry Schein Products	Orthodontics Group	Amanda Hall
Vicki Babilonia	Supervisor, Customer Service - Ortho	Henry Schein Products Group	Orthodontics Group	Annie Cavazos Parra
Jennifer Ellsworth	Customer Care Lead - Ortho	Henry Schein Products	Orthodontics Group	Annie Cavazos Parra
Geneva Martin	Aligner Specialist, International - Orthodontics	Henry Schein Products Group	Orthodontics Group	Annie Cavazos Parra
Jonathan Garcia	Aligner Customer Care Representative - Ortho	Henry Schein Products Group	Orthodontics Group	Annie Cavazos Parra
Lisa Mannarino	Strategic Accounts Specialist-Ortho	Henry Schein Products Group	Orthodontics Group	Austin Shockley
Jarret Bilbrey	Executive Orthodontic Sales Specialist	Henry Schein Products Group	Orthodontics Group	Austin Shockley
Brynne Collard	Sr Orthodontic Sales Specialist	Henry Schein Products Group	Orthodontics Group	Austin Shockley
Mandy Deus (On Leave)	Sr Orthodontic Sales Specialist	Henry Schein Products Group	Orthodontics Group	Austin Shockley
Cory Tate	Senior Group Practice Sales Specialist - Ortho	Henry Schein Products Group	Orthodontics Group	Austin Shockley
Peter Brooks	Senior Group Practice Sales Specialist - Ortho	Henry Schein Products Group	Orthodontics Group	Austin Shockley
Carrie Gabriel	Orthodontic Sales Specialist	Henry Schein Products	Orthodontics Group	Austin Shockley
Nicole Rajek	Sr Director, Regulatory Affairs & Quality Assurance	Henry Schein Products Group	Orthodontics Group	Barry Thornton
Thomas Arnold	Sr Regulatory Affairs Specialist	Henry Schein Products	Orthodontics Group	Carl Mazzolini
Lucy Salazar	Regulatory Labeling Specialist II	Henry Schein Products Group	Orthodontics Group	Carl Mazzolini
Lisette Ignacio	Regulatory Labeling Specialist I	Henry Schein Products Group	Orthodontics Group	Carl Mazzolini
LEWIS CERTAIN	Regulatory Affairs Specialist II - Ortho	Corporate	Regulatory	Carl Mazzolini
Annie Cavazos Parra	Manager, Customer Care Team	Henry Schein Products Group	Orthodontics Group	Cory Cooper

Karen Trumbo	Strategic Accounts Specialist-Ortho	Henry Schein Products Group	Orthodontics Group	Cory Cooper
Michael Gadachy	Sr Manager, Global Inside Sales - Orthodontics	Henry Schein Products Group	Orthodontics Group	Cory Cooper
Mitchellee Delosreyes	Strategic Accounts Specialist-Ortho	Henry Schein Products Group	Orthodontics Group	Cory Cooper
Crystal Kunzler	Strategic Account Executive - Ortho	Henry Schein Products Group	Orthodontics Group	Cory Cooper
Kelsey Becker	Sr Strategic Account Manager - Ortho	Henry Schein Products Group	Orthodontics Group	Cory Cooper
Austin Shockley	Manager, Group Practice Sales	Henry Schein Products Group	Orthodontics Group	Cory Cooper
Kimmy Adams	Strategic Accounts Specialist-Ortho	Henry Schein Products Group	Orthodontics Group	Cory Cooper
Coley Blomquist	Associate Strategic Account Manager - Ortho	Henry Schein Products Group	Orthodontics Group	Crystal Kunzler
Megan Martinson	Clinical Product Specialist	Henry Schein Products	Orthodontics Group	Crystal Kunzler
Christian Galt	Associate Marketing Manager - Orthodontics	Henry Schein Products Group	Orthodontics Group	Danielle Laymon
Katie Withers	Manager, Marketing - Core Orthodontics	Henry Schein Products Group	Orthodontics Group	Danielle Laymon
Sean Standen	Web Developer, Ortho	Henry Schein Products	Orthodontics Group	Danielle Laymon
Jamie Morness	Sr Product Manager - Ortho	Henry Schein Products	Orthodontics Group	Gretchen Bahadur
Oda Becerra	Sr Human Resources Manager	Corporate	Human Resources	Janine Martelli
Anna Riles	International Inside Sales Rep-Ortho Tech	Henry Schein Products Group	Orthodontics Group	Janira Taveras
Jacinthe Balos	Sales/Training Specialist	Henry Schein Products	Orthodontics Group	Janira Taveras
Gabe Salas	Sr Mechanical Designer	Henry Schein Products	Orthodontics Group	Jim Thompson
Tejdeep Riat	Sr Manager, Engineering	Henry Schein Products	Orthodontics Group	Jim Thompson
Nikunj Gala	Sr Design Quality Engineer, Orthodontics	Henry Schein Products Group	Orthodontics Group	Jim Thompson
Ricardo Hiram Hernandez Rueda	Quality Engineer - Ortho	Henry Schein Products Group	Orthodontics Group	John Williams
Estela Flores	Document and Configuration Management Specialist	Henry Schein Products Group	Orthodontics Group	John Williams
LIZBETH ILESCAS VILLAVICENCIO	Quality Engineer - Ortho	Henry Schein Products Group	Orthodontics Group	John Williams
CHRISTOPHER SCHMIERER	IT Support Services Technician II	Henry Schein Products Group	Orthodontics Group	Josh Parker

Jenny Smith	Administrative Assistant	Henry Schein Products	Orthodontics Group	Justin Davis
Janira Taveras	International Sales Manager - Ortho	Henry Schein Products Group	Orthodontics Group	Justin Davis
Alma Ricardo	Manufacturing Planner I - Ortho	Henry Schein Products	Orthodontics Group	Kim Ramer
Julio Aguilar Rivas	Manager, Planning - Ortho	Henry Schein Products	Orthodontics Group	Kim Ramer
Lucy Arciniega	Buyer II - Ortho	Henry Schein Products	Orthodontics Group	Kim Ramer
Amanda Hall	Associate Manager, Aligner Operations	Henry Schein Products Group	Orthodontics Group	Kim Ramer
Cody Stanley	Buyer I - Ortho	Henry Schein Products	Orthodontics Group	Kim Ramer
Ed Schneider	Sr Business Data Analyst - Ortho	Henry Schein Products Group	Orthodontics Group	Kimberly Rogert (On Leave)
Antonio De La O	Associate Manager, Finance - Ortho	Henry Schein Products Group	Orthodontics Group	Kimberly Rogert (On Leave)
Max Gerken	Financial Analyst - Ortho	Henry Schein Products Group	Orthodontics Group	Kimberly Rogert (On Leave)
Eric Chou	Sr Accountant I, Orthodontics Controllership	Henry Schein Products Group	Orthodontics Group	Kimberly Rogert (On Leave)
Marie Hunter	Sr HR Business Partner	Corporate	Human Resources	Kyleen Huber
Shelly Permann	Executive Inside Sales Rep - Ortho	Henry Schein Products Group	Orthodontics Group	Michael Gadachy
Carl Mazzolini	Manager, Regulatory Affairs	Henry Schein Products	Orthodontics Group	Nicole Rajek
John Williams	Associate Manager, Quality Assurance	Henry Schein Products Group	Orthodontics Group	Nicole Rajek
Brian Brown	Supervisor, Manufacturing - Ortho	Henry Schein Products Group	Orthodontics Group	Pamela Benson
Kim Ramer	Director, Supply Chain - Ortho	Henry Schein Products	Orthodontics Group	Pamela Benson
John Jury	US Manager, Tool Room	Henry Schein Products	Orthodontics Group	Pamela Benson
Michelle Rais	Program Specialist, Global Professional Education	Henry Schein Products Group	Orthodontics Group	Richard Stahr
John Lawrence	Associate Manufacturing Engineer	Henry Schein Products Group	Orthodontics Group	Tejdeep Riat
Jacob Matis	Associate Engineer	Henry Schein Products Group	Orthodontics Group	Tejdeep Riat
Zach Meli	VP & GM, Orthopedics and Orthodontics	Corporate	HSG	Tom Popeck
Ingrid Mota	US Sr. Customer Service Representative- Ortho	Henry Schein Products Group	Orthodontics Group	Vicki Babilonia

Pamela Benson	Executive Director, Operations Excellence and Material Management	Henry Schein Products Group	Orthodontics Group	Yvonne Smith
Adolfo Alvarado	US Sr Director, Finance – Global Orthodontics	Corporate	HSG	Zach Meli
Cory Cooper	Director, Strategic Accounts - Orthodontics	Henry Schein Products Group	Orthodontics Group	Zach Meli
Danielle Laymon	Sr Manager, Marketing - Core Orthodontics	Henry Schein Products Group	Orthodontics Group	Zach Meli
Gretchen Bahadur	Sr Manager, Global Product Management	Henry Schein Products Group	Orthodontics Group	Zach Meli
Maria Gaby Soechtig Aponte	Orthodontic Specialist	Henry Schein Products Group	Orthodontics Group	Zach Meli
Omar Mirza,	Labeling Specialist	Temporary Employee	Marquee Staffing	Carl Mazzolini
Anadelia Perez,	Labeling Specialist	Temporary Employee	Ultimate Staffing Service	Carl Mazzolini
Nadia Dannhauser,	Regulatory Specialist	Temporary Employee	Ultimate Staffing Service	Carl Mazzolini
Christian Hernandez	Quality Engineer	Temporary Employee	Ultimate Staffing Service	Edgar Flores

4CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH03695	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Pangea Pharmaceuticals, LLC

Physical Address: 201 Union Lane, Suite B

City: Brielle State: NJ Zip: 08730

Mailing Address (if different from physical address): c/o State License Servicing, Inc., 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: www.pangeapharm.com

Name of Designated Representative (DR): Denise Marie Berger

Licensing Company Email: PAN@slsny.com DR Email: DBerger@pangeapharm.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☒ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Clinics, Institutions & US Government		☒ Others: Manufacturer - Virtual

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A - No discipline to report

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: AXIA MEDICAL SOLUTIONS LLC
Address: 10691 King William Dr City: Dallas State: TX Zip: 75220

Name: OPTION CARE HEALTH, INC
Address: 3000 LAKESIDE DRIVE, SUITE 300 City: BANNOCKBURN State: IL Zip: 60015

Name: HOSPITAL PHARMACEUTICAL CONSUL
Address: 5100 COMMERCE PKWY REAL VALUE City: SAN ANTONIO State: TX Zip: 78218-55

Name: KEYSOURCE LLC
Address: 7820 PALACE DRIVE City: CINCINNATI State: OH Zip: 45249

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): Pangea Pharmaceuticals Holdings, LLC (100%)
Corporation/Organization Name: Pangea Pharmaceuticals, LLC
Mailing Address: c/o State License Servicing, Inc., 225 Dolson Avenue, 4th Floor
City: Middletown State: NY Zip: 10940
Telephone: (845) 544-2482 Email: PAN@slsny.com
Contact Person Name: Christine Cannon

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: Labeler Code: 81279	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Pangea Pharmaceuticals, LLC

Facility Name

Anthony Joseph LaViola

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

08/24/26

Date

Board Use Only	Date Received: 9/11/26	Amount: $ 1000 Ck. 2776

Company Particulars

Pangea Pharmaceuticals, LLC

Corporate Address: 201 Union Lane, Suite B, Brielle, NJ 08730 USA
FEIN: 83-4468762
www.pangeapharm.com

Drug Labeler Code: 81279
Incorporation State: DE
Incorporation Date: 4/18/2019

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
ULB	201 Union Lane Suite B Brielle, NJ 08730 County: Monmouth	N/A	N/A - No CS	117751012	No	(866) 272-6432	(954) 754-6432

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Anthony Joseph LaViola	[redacted]	CEO	No	[redacted]		
Stephen Paul Flood		Co-Founder - President	No			

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Pangea Pharmaceuticals Holdings, LLC	100 NE 3rd Avenue Suite 615 Fort Lauderdale, FL 33301	N/A	100%	N/A	42-2428555	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Anthony Joseph LaViola	[redacted]	CEO	No	[redacted]		

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
Vcorp Services, LLC			

3PLS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Eversana Life Science Services, LLC	4580 Mendenhall Rd Memphis, TN 38141					
Rainbow Gold, Inc	115 Grimes Drive Guntersville, AL 35976					

Proof of Labeler Code

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

National Drug Code Directory

Current through June 23, 2026

You have searched Finished drug products

Search Results: '81279'

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page** **Search for text in the table:**

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Pr Ty
Bucapsol	81279-122-60	7.5 mg/1	CAPSULE	ORAL	ANDA218628	PANGEA PHARMACEUTICALS, LLC	81279-122	Buspirone Hydrochloride	BUSPIRONE	HUM PRE DRU
Bucapsol	81279-122-30	7.5 mg/1	CAPSULE	ORAL	ANDA218628	PANGEA PHARMACEUTICALS, LLC	81279-122	Buspirone Hydrochloride	BUSPIRONE	HUM PRE DRU
Bucapsol	81279-123-30	10 mg/1	CAPSULE	ORAL	ANDA218628	PANGEA PHARMACEUTICALS, LLC	81279-123	Buspirone Hydrochloride	BUSPIRONE	HUM PRE DRU
Bucapsol	81279-123-60	10 mg/1	CAPSULE	ORAL	ANDA218628	PANGEA PHARMACEUTICALS, LLC	81279-123	Buspirone Hydrochloride	BUSPIRONE	HUM PRE DRU
Bucapsol	81279-124-60	15 mg/1	CAPSULE	ORAL	ANDA218628	PANGEA PHARMACEUTICALS, LLC	81279-124	Buspirone Hydrochloride	BUSPIRONE	HUM PRE DRU
Bucapsol	81279-124-30	15 mg/1	CAPSULE	ORAL	ANDA218628	PANGEA PHARMACEUTICALS, LLC	81279-124	Buspirone Hydrochloride	BUSPIRONE	HUM PRE DRU
Dexamethasone	81279-117-60	.25 mg/1	TABLET	ORAL	ANDA088149	Pangea Pharmaceuticals, LLC	81279-117	Dexamethasone	DEXAMETHASONE	HUM PRE DRU
Ergomar	81279-104-03	2 mg/1	TABLET	ORAL	ANDA087693	Pangea Pharmaceuticals LLC	81279-104	Ergotamine Tartrate	ERGOTAMINE TARTRATE	HUM PRE DRU

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Pr Ty
Ergomar	81279-104-20	2 mg/1	TABLET	ORAL	ANDA087693	Pangea Pharmaceuticals LLC	81279-104	Ergotamine Tartrate	ERGOTAMINE TARTRATE	HUM PRE DRU
GABAPENTIN	81279-126-60	200 mg/1	CAPSULE	ORAL	ANDA219319	Pangea Pharmaceuticals, LLC	81279-126	GABAPENTIN	GABAPENTIN	HUM PRE DRU
Sdamlo	81279-133-10	2.5 mg/2.5mg	SOLUTION	ORAL	NDA219531	Pangea Pharmaceuticals, LLC	81279-133	amlodipine	AMLODIPINE BESYLATE	HUM PRE DRU
Sdamlo	81279-134-10	5 mg/5mg	SOLUTION	ORAL	NDA219531	Pangea Pharmaceuticals, LLC	81279-134	amlodipine	AMLODIPINE BESYLATE	HUM PRE DRU
Sdamlo	81279-135-10	10 mg/10mg	SOLUTION	ORAL	NDA219531	Pangea Pharmaceuticals, LLC	81279-135	amlodipine	AMLODIPINE BESYLATE	HUM PRE DRU
Selenious Acid	81279-106-05	40 ug/mL	INJECTION, SOLUTION	INTRAVENOUS		Pangea Pharmaceuticals, LLC	81279-106	Selenious Acid	SELENIUM	HUM PRE DRU
URSOLIGN	81279-130-60	150 mg/1	CAPSULE	ORAL	ANDA210344	Pangea Pharmaceuticals, LLC	81279-130	ursodiol	URSODIOL	HUM PRE DRU

Showing 1 to 15 of 15 entries

Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

1800

DE Incorp Good Standing

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PANGEA PHARMACEUTICALS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWELFTH DAY OF AUGUST, A.D. 2026.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 204813998

Date: 08-12-26

7380686 8300

SR# 20264045377

You may verify this certificate online at corp.delaware.gov/authver.shtml

Home State Verification of License

Registration Number: 5006007 **Registered As:** Distributor

Information Recorded in the System as of 06/23/2026

Name: PANGEA PHARMACEUTICALS, LLC

New Jersey Department of Health

DBA:

Address: 201 UNION LN STE B BRIELLE, NJ 08730

Original Issue Date: 01/18/2023 **Expiration Date:** 01/31/2027

Current Issue Date: 12/08/2025

Disciplines: No

Permit Status: Active

Home State (NJ) No official VOL Correspondence

Mackenzie Winne - All Ope... › 77477

☆ Reply Add note Forward Close Merge Delete ⋮

Overdue

RE: [EXTERNAL] Verification of Licensure

DOH-PHFPP reported via email

Add summary

DOH-PHFPP reported via email
18 days ago (Fri, 11 Sep 2020 at 4:44 PM)

To: "'SLSNYSupport.com'" <help@slsnysupport.com>

Thank you. Due to limited resources, the NJ Department of Health cannot complete license verification forms for other states. Please utilize the online verification system on our webpage: https://nj.gov/health/ceohs/food-drug-safety/medical-device-reg/

Jennifer Steffee | Public Health Representative
NJ Department of Health | Public Health & Food Protection
PO Box 369 | 135 E State St | Trenton, NJ 08625
609.913.5150 | http://nj.gov/health/ceohs

Bond Continuance

VERIFICATION CERTIFICATE FOR INDEFINITE TERM SURETY BOND

THIS IS TO CERTIFY that Bond No. 2341217 **issued by** Swiss Re Corporate Solutions **dated this** 27th **day of** May, 2026, **in the amount of** ($100,000.00), **on behalf of** Pangea Pharmaceuticals, LLC **(as Principal), and in favor of** Nevada State Board of Pharmacy **(as Obligee), for** _____ **covers a term which began on the** 15th **day of** March, 2024, **and ends only with the cancellation of said bond or other legal termination thereof; and that the said bond remains in effect, subject to all its agreements, conditions and limitations.**

Signed, sealed and dated:

Donna M. Chiancone

BY: Donna M. Chiancone

Current Term of Bond: March 15, 2026 **to** March 15, 2027

SWISS RE CORPORATE SOLUTIONS

SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION ("SRCSAIC")
SWISS RE CORPORATE SOLUTIONS PREMIER INSURANCE CORPORATION ("SRCSPIC")

GENERAL POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, THAT SRCSAIC, a corporation duly organized and existing under laws of the State of Missouri, and having its principal office in the City of Kansas City, Missouri, and SRCSPIC, a corporation organized and existing under the laws of the State of Missouri and having its principal office in the City of Kansas City, Missouri, each does hereby make, constitute, and appoint:

DONNA M. CHIANCONE, TRAVIS W. SHAFFER, LORI N. BAYBUTT, KATHLEEN A. PETERSEN,

and LAURA A. RICKETT

JOINTLY OR SEVERALLY

Its true and lawful Attorney(s)-in-Fact to make, execute, seal and deliver, for and on its behalf and as its act and deed, bonds, consents of surety, or other writings obligatory in the nature of a bond on behalf of each of said Companies, as surety, on contracts of suretyship as are or may be required or permitted by law, regulation, contract or otherwise, provided that no bond or undertaking or contract or suretyship executed under this authority shall exceed the amount of:

TWO HUNDRED MILLION ($200,000,000.00) DOLLARS

This Power of Attorney is granted and is signed by facsimile under and by the authority of the following Resolutions adopted by the Boards of Directors of both SRCSAIC and SRCSPIC at meetings duly called and held on the 18th of November 2021:

"RESOLVED, that any two of the President, any Managing Director, any Senior Vice President, any Vice President, the Secretary or any Assistant Secretary be, and each or any of them hereby is, authorized to execute a Power of Attorney qualifying the attorney named in the given Power of Attorney to execute on behalf of the Corporation bonds, undertakings and all contracts of surety, and that each or any of them hereby is authorized to attest to the execution of any such Power of Attorney and to attach therein the seal of the Corporation; and it is

FURTHER RESOLVED, that the signature of such officers and the seal of the Corporation may be affixed to any such Power of Attorney or to any certificate relating thereto by facsimile, and any such Power of Attorney or certificate bearing such facsimile signatures or facsimile seal shall be binding upon the Corporation when so affixed and in the future with regard to any bond, undertaking or contract of surety to which it is attached."

SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION CORPORATE SEAL 1973 MISSOURI

By _____
David Satory, Senior Vice President of SRCSAIC & Senior Vice President of SRCSPIC

By _____
Gabriel Jacquez, Senior Vice President of SRCSAIC & Senior Vice President of SRCSPIC

SWISS RE CORPORATE SOLUTIONS PREMIER INSURANCE CORPORATION CORPORATE SEAL MISSOURI

IN WITNESS WHEREOF, SRCSAIC and SRCSPIC have caused their official seals to be hereunto affixed, and these presents to be signed by their authorized officers this 26th day of January, 2026.

Swiss Re Corporate Solutions America Insurance Corporation
Swiss Re Corporate Solutions Premier Insurance Corporation

State of Illinois
County of Cook ss

On this 26th day of January, 2026, before me, a Notary Public personally appeared David Satory, Senior Vice President of SRCSAIC and Senior Vice President of SRCSPIC, and Gabriel Jacquez, Senior Vice President of SRCSAIC and Senior Vice President of SRCSPIC, personally known to me, who being by me duly sworn, acknowledged that they signed the above Power of Attorney as officers of and acknowledged said instrument to be the voluntary act and deed of their respective companies.

OFFICIAL SEAL
KAREN M SZWEDA
Notary Public, State of Illinois
Commission No. 978628
My Commission Expires September 26, 2027

Karen M. Szweda, Notary

I, Jeffrey Goldberg, the duly elected Senior Vice President and Assistant Secretary of SRCSAIC and SRCSPIC, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney given by said SRCSAIC and SRCSPIC, which is still in full force and effect.

IN WITNESS WHEREOF, I have set my hand and affixed the seals of the Companies this 27th day of May, 2026.

Jeffrey Goldberg, Senior Vice President &
Assistant Secretary of SRCSAIC & SRCSPIC

Swiss Re
Corporate Solutions
SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION

1450 American Lane, Suite 1100, SCHAUMBURG, ILLINOIS 60173
800/338-0753

SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION
A Missouri Corporation

BALANCE SHEET AS OF DECEMBER 31, 2025
(Statutory Basis)

Valuation of securities on National Association of Insurance Commissioner Basis

ASSETS		LIABILITIES	
Cash	496,907,141	Reserve for Unearned Premiums	283,797,146
Bonds	1,843,360,105	Reserve for Losses and Loss Adjustment Expenses	810,013,224
Common Stock	271,609,096	Funds Withheld	288,682,930
Other Invested Assets	0	Taxes and Other Liabilities	1,108,764,689
Other Admitted Assets	1,111,105,879	Surplus	1,231,724,234
TOTAL ADMITTED ASSETS	3,722,982,223	**TOTAL LIABILITIES & POLICYHOLDERS' SURPLUS**	3,722,982,223

The undersigned, being duly sworn, says: That he is Vice President of Swiss Re Corporate Solutions America Insurance Corporation, Kansas City, Missouri that said company is a corporation duly organized, existing by virtue of the Laws of the State of Missouri and that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress approved; July 1947 6 U.S.C. sec. 6-13; and that to the best of his knowledge and belief the above statement is a full, true and correct statement of the financial condition of the said Company on the 31st day of December, 2025.

Gabe Jacquez, Senior Vice President
Swiss Re Corporate Solutions America Insurance Corporation

Subscribed and sworn before me,
this 28th day of February, 2026

Notary Public

OFFICIAL SEAL
KAREN M SZWEDA
Notary Public, State of Illinois
Commission No. 978628
My Commission Expires September 26, 2027

Bond w/ Continuance

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 2341217

Application/License No. _____

Pangea Pharmaceuticals, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 201 Union Lane Suite B, Brielle, NJ 08730 (Address of Applicant/Principal), as PRINCIPAL, and Swiss Re Corporate Solutions America Insurance Corporation (Surety Company), a corporation organized under the laws of the state of Missouri (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1200 Main Street, Suite 800, Kansas City, MO 64105-2478 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 15, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 15th day of March, 2024.

Pangea Pharmaceuticals, LLC
APPLICANT/PRINCIPAL COMPANY

Swiss Re Corporate Solutions America Insurance Corporation
SURETY

Authorized Representative

Surety Company's Representative

Donna M. Chiancone, Attorney-in-fact
print name

SEAL

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Lori N. Baybutt, Witness to Surety

Witness

Witness Kevin Baybutt, Witness to Surety

Countersigned by:

Nevada Resident Agent
Donna M. Chiancone

NV Non-Resident License # 545412

Posted February 20, 2020

SWISS RE CORPORATE SOLUTIONS

SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION ("SRCSAIC")
SWISS RE CORPORATE SOLUTIONS PREMIER INSURANCE CORPORATION ("SRCSPIC")

GENERAL POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, THAT SRCSAIC, a corporation duly organized and existing under laws of the State of Missouri, and having its principal office in the City of Kansas City, Missouri, and SRCSPIC, a corporation organized and existing under the laws of the State of Missouri and having its principal office in the City of Kansas City, Missouri, each does hereby make, constitute, and appoint:

DONNA M. CHIANCONE, TRAVIS W. SHAFFER, LORI N. BAYBUTT, KATHLEEN A. PETERSEN, and LAURA A. RICKETT

JOINTLY OR SEVERALLY

Its true and lawful Attorney(s)-in-Fact, to make, execute, seal and deliver, for and on its behalf and as its act and deed, bonds or other writings obligatory in the nature of a bond on behalf of each of said Companies, as surety, on contracts of suretyship as are or may be required or permitted by law, regulation, contract or otherwise, provided that no bond or undertaking or contract or suretyship executed under this authority shall exceed the amount of:

TWO HUNDRED MILLION ($200,000,000.00) DOLLARS

This Power of Attorney is granted and is signed by facsimile under and by the authority of the following Resolutions adopted by the Boards of Directors of both SRCSAIC and SRCSPIC at meetings duly called and held on the 9th of May 2012:

"RESOLVED, that any two of the President, any Managing Director, any Senior Vice President, any Vice President, the Secretary or any Assistant Secretary be, and each or any of them hereby is, authorized to execute a Power of Attorney qualifying the attorney named in the given Power of Attorney to execute on behalf of the Corporation bonds, undertakings and all contracts of surety, and that each or any of them hereby is authorized to attest to the execution of any such Power of Attorney and to attach therein the seal of the Corporation; and it is

FURTHER RESOLVED, that the signature of such officers and the seal of the Corporation may be affixed to any such Power of Attorney or to any certificate relating thereto by facsimile, and any such Power of Attorney or certificate bearing such facsimile signatures or facsimile seal shall be binding upon the Corporation when so affixed and in the future with regard to any bond, undertaking or contract of surety to which it is attached."

SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION CORPORATE SEAL 1973 MISSOURI

SWISS RE CORPORATE SOLUTIONS PREMIER INSURANCE CORPORATION CORPORATE SEAL MISSOURI

By_____
Erik Janssens, Senior Vice President of SRCSAIC & Senior Vice President of SRCSPIC

By_____
Gerald Jagrowski, Vice President of SRCSAIC & Vice President of SRCSPIC

IN WITNESS WHEREOF, SRCSAIC and SRCSPIC have caused their official seals to be hereunto affixed, and these presents to be signed by their authorized officers this 10TH day of NOVEMBER, 2022

Swiss Re Corporate Solutions America Insurance Corporation
Swiss Re Corporate Solutions Premier Insurance Corporation

State of Illinois
County of Cook ss

On this 10TH day of 15th, 20 22, before me, a Notary Public personally appeared Erik Janssens, Senior Vice President of SRCSAIC and Senior Vice President of SRCSPIC and Gerald Jagrowski, Vice President of SRCSAIC and Vice President of SPCSPIC, personally known to me, who being by me duly sworn, acknowledged that they signed the above Power of Attorney as officers of and acknowledged said instrument to be the voluntary act and deed of their respective companies.

OFFICIAL SEAL
CHRISTINA MANISCO
NOTARY PUBLIC, STATE OF ILLINOIS
My Commission Expires March 28, 2026

Christina Manisco, Notary

I, Jeffrey Goldberg, the duly elected Senior Vice President and Assistant Secretary of SRCSAIC and SRCSPIC, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney given by said SRCSAIC and SRCSPIC, which is still in full force and effect.
IN WITNESS WHEREOF, I have set my hand and affixed the seals of the Companies this 15th day of March, 20 24.

Jeffrey Goldberg, Senior Vice President & Assistant Secretary of SRCSAIC and SRCSPIC

Swiss Re
Corporate Solutions
SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION

1450 American Lane, Suite 1100, SCHAUMBURG, ILLINOIS 60173
800/338-0753

SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION
A Missouri Corporation

BALANCE SHEET AS OF DECEMBER 31, 2022
(Statutory Basis)

Valuation of securities on National Association of Insurance Commissioner Basis

ASSETS		**LIABILITIES**	
Cash	424,718,741	Reserve for Unearned Premiums	149,350,540
Bonds	797,801,222	Reserve for Losses and Loss Adjustment Expenses	235,835,273
Common Stock	315,720,039	Funds Withheld	92,137,049
Other Invested Assets	34,744	Taxes and Other Liabilities	429,886,411
Other Admitted Assets	385,652,521	Surplus	1,016,717,994
TOTAL ADMITTED ASSETS	1,923,927,267	**TOTAL LIABILITIES & POLICYHOLDERS' SURPLUS**	1,923,927,267

The undersigned, being duly sworn, says: That he is Vice President of Swiss Re Corporate Solutions America Insurance Corporation, Kansas City, Missouri that said company is a corporation duly organized, existing by virtue of the Laws of the State of Missouri and that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress approved, July 1947 6 U.S.C. sec. 6-13; and that to the best of his knowledge and belief the above statement is a full, true and correct statement of the financial condition of the said Company on the 31st day of December, 2022.

Gerald Jagrowski, Vice President
Swiss Re Corporate Solutions America Insurance Corporation

Subscribed and sworn before me,
this 18th day of April, 2023

Notary Public

Official Seal
Kenneth Michael Mestny
Notary Public State of Illinois
My Commission Expires 10/19/2026

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Pangea Pharmaceuticals, LLC

Pharmacy/Wholesaler License # (if applicable): WH03695

Physical Address: 201 Union Lane, Suite B

City: Brielle State: NJ Zip: 08730

Mailing Address (if different from physical address): c/o State License Servicing, Inc. 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: www.pangeapharm.com

Licensing Company Email: PAN@slsny.com

Section 2: Personal Information

First: Denise Middle: Marie Last: Berger

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Addres: [redacted]

City: Pt. Pleasant State: NJ Zi: [redacted]

Telephone: (866) 272-6432 Email: DBerger@pangeapharm.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
CABRINI UNIVERSITY			09/81 – 05/85	
Address		City	State	Zip
610 KING OF PRUSSIA ROAD		RADNOR	PA	19087
Diploma/Degree obtained, if any				
BACHELOR'S DEGREE - FRENCH & BUSINESS ADMINISTRATION				
School Name			From - To (MM/YY – MM/YY)	
POINT PLEASANT BEACH HIGH SCHOOL			09/77 - 06/81	
Address		City	State	Zip
700 TRENTON AVE		POINT PLEASANT BEACH	NJ	08742
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
G. HAROLD ANDRIM ELEMENTARY SCHOOL			09/68 - 06/77	
Address		City	State	Zip
401 NIBLICK STREET		POINT PLEASANT BEACH	NJ	08742
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2007 - Present	[redacted]	Pt. Pleasant	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Pangea Pharmaceuticals, LLC			07/26 - PRESENT
Business Address	**City**	**State**	**Zip**
201 Union Lane, Suite B	Brielle	NJ	08730
Phone	**Title**	**Number of Employed Hours**	
(866) 272-6432	Commercial & Supply Chain Manager	56	
Description of Duties			
COMMERCIAL OPERATIONS, SUPPLY CHAIN MANAGEMENT, LOGISTICS, DISTRIBUTION, INVENTORY CONTROL, PRODUCT LAUNCH SUPPORT, FORECASTING, REGULATORY SUPPORT, STATE LICENSING			

Business Name			From - To (MM/YY – MM/YY)
GRANARD PHARMACEUTICALS, LLC			08/10 - 04/26
Business Address	**City**	**State**	**Zip**
1967 HIGHWAY 34, SUITE 103	WALL	NJ	07719
Phone	**Title**	**Number of Employed Hours**	
(732) 292-2661	DIRECTOR OF OPERATIONS	33,280	
Description of Duties			
COMMERCIAL OPERATIONS, SUPPLY CHAIN MANAGEMENT, LOGISTICS, DISTRIBUTION, INVENTORY CONTROL, FORECASTING, REGULATORY SUPPORT, STATE LICENSING, OFFICE ADMIN.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

N/A

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A - None to disclose.

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Denise Marie Berger, **certify that as the designated representative for**

Pangea Pharmaceuticals, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DB I am at least 21 years of age;
3. DB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Denise Marie Berger
Print Name (First, Last)

Denise Marie Berger
Original Signature (electronic, copies or stamps not accepted)

8/14/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Denise Marie Berger

Print Name (First, Last)

Denise M. Berger — 8/14/2026

Original Signature (electronic, copies or stamps not accepted) — Date

Denise Marie Berger

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Ocean

I, DENISE BERGER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Denise M. Berger — 8/14/2026

Original Signature — **Date**

Denise Marie Berger

Subscribed and Sworn to before me this 14 day of August.

Notary Public Signature

COLLEEN B. WILSON
Notary Public, State of New Jersey
Commission # 50183297
My Commission Expires 1/24/2027

(Seal)

Employee List

PANGEA PHARMACEUTICALS

June 1, 2026

Nevada List of Employees:

Anthony Laviola	CEO
Pete Licata	CFO
Jennifer Moura	PM
Vish Nooty	Executive Director
Steve Flood	Co-Founder & President
Brit Hiene	Product Analyst
Jennifer Berkery	Sales and Marketing Trade Associate
Jeremy Plasencia	Technical Support Specialist

PANGEA PHARMACEUTICALS

Pangea Pharmaceuticals, LLC
201 Union Lane, Ste B
Brielle, NJ 08730

Ofc: (866) 272-6432
Fax: (413) 556-6632

Website: www.pangeapharm.com
Email: info@pangeapharm.com

PANGEA
PHARMACEUTICALS

June 1, 2026

Nevada List of Employees:

Anthony Laviola	CEO
Pete Licata	CFO
Jennifer Moura	PM
Vish Nooty	Executive Director
Steve Flood	Co-Founder & President
Brit Hiene	Product Analyst
Jennifer Berkery	Sales and Marketing Trade Associate
Jeremy Plasencia	Technical Support Specialist

PANGEA
PHARMACEUTICALS

Pangea Pharmaceuticals, LLC
201 Union Lane, Ste B
Brielle, NJ 08730

Ofc: (866) 272-6432
Fax: (413) 556-6632

Website: www.pangeapharm.com
Email: info@pangeapharm.com

4DD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10)

Section 1: General Information

Facility Name: SteriMax USA Inc.

Physical Address: 1136 Highway 22

City: Mountainside State: NJ Zip: 07092

Mailing Address (if different from physical address): 1136 Highway 22

City: Mountainside State: New Jersey Zip: 07092

Telephone: 877-373-4657 Website: https://sterimaxinc.com

Name of Designated Representative (DR): Karen Andrus

Licensing Company Email: kandrus@sterimaxinc.com DR Email: kandrus@sterimaxinc.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies ☐ Practitioners ☒ Hospitals ☐ Wholesalers ☐ Veterinarians ☐ Others:	☒ Dangerous Drugs ☐ Controlled Substances ☐ [a]Medical Products (medical devices, equipment, supplies, gases) ☐ Others:	☐ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ☒ Others: Virtual Manufacturer

Section 2: ONLY COMPLETE THIS SECTION IF THE COMPANY IS WHOLESALING [a]Medical Products (medical devices, equipment, supplies and gases). Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 3 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 4: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: NA

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): SteriMax Inc.

Corporation/Organization Name: SteriMax USA Inc.

Mailing Address: 1136 Highway 22

City: Mountainside State: New Jersey Zip: 07092

Telephone: 877-373-4657 Email: kandrus@sterimaxinc.com

Contact Person Name: Karen Andrus

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	x	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 10: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale [a]Medical Products (medical devices, equipment, supplies, gases). (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Products (medical devices, equipment, supplies, gases), supply a copy of proof of insurance (NAC 639.6957).** The Medical Products wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 9)				
• **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20NRS%20639.500%20-%20Effective%2001.07.2026%20-%20Wholesaler%20-%20Post%20on%201.26.26.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

SteriMax USA Inc.

Facility Name

Edward Rajasigham

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

June 23, 2026

Date

Board Use Only	Date Received: 8/17/26	Amount: $1000 ch 5860

STERIMAX

SteriMax USA Inc.'s product had been registered with FDA by their parent company, SteriMax Inc., prior to the USA entity being formed. Title is owned by SteriMax USA Inc. once product enters the US and the labeler code associated with their product, Claforan, will belong to SteriMax Inc. SteriMax USA Inc. will be reflected on the product label.

Product details of Claforan are as follows:

Product List

Labeler Code: 21586

Molecular Name: Cefotaxime Sodium

NDC: 21586-011, 21586-012

Dosage Form/Strength: 10 VIAL in 1 PACKAGE (21586-011-02) / 1 POWDER, FOR SOLUTION in 1 VIAL (21586-011-01). 10 VIAL in 1 PACKAGE (21586-012-02) / 1 POWDER, FOR SOLUTION in 1 VIAL (21586-012-01).

STERIMAX

Description of Operations

SteriMax USA Inc. is a virtual manufacturer. SteriMax USA Inc.'s products are manufactured by a contract manufacturer and will be distributed to hospital pharmacies by their third-party logistics provider, Direct Success Inc., who is licensed to ship pharmaceutical products into your state.

Contract Manufacturer Information:
We are using the following contract manufacturer to produce our product:

Qilu Antibiotics Pharmaceutical Co., LTD
No.849 Dongjia Town, Licheng District, Jinan
Shandong, China 250105
FDA Establishment Number: 3009831352

Contact Person: Wang Li
Contact Number: 86 531 83128623

Qilu Antibiotics Pharmaceutical Co., LTD manufactures SteriMax USA Inc.'s product and packages finished product. At no time does Qilu Antibiotics Pharmaceutical Co., LTD own the product, contract with SteriMax USA Inc.'s customers, invoice, nor sell a SteriMax USA Inc. product. SteriMax USA Inc. product is not a controlled substance.

Labeler Code:
21586

Third Party Logistic information:
For distribution into the commercial supply channels, Direct Success Inc. acts as SteriMax USA Inc.'s third-party logistics (3PL) provider to manage the storage and distribution of SteriMax USA Inc.'s product-throughout the United States. Direct Success Inc.'s address is:

Direct Success Inc.
1710 Highway 34
Wall Township, NJ 07727

Contact: Shannon Messina Phone Number: 732-919-1234

SteriMax USA Inc. has 1 employee working on site during normal business hours.
SteriMax USA Inc.'s hours of operation are 10:00 am – 2:00 pm Monday through Thursday.
SteriMax USA Inc.'s records are stored at Direct Success Inc.
SteriMax USA Inc.'s facility square footage is 700 square feet.

STERIMAX

Company Information

Company Name: SteriMax USA Inc.
Address: 1136 Highway 22
City, State, Zip: Mountainside, NJ 07092
Phone: 877-373-4657
Website: http:/www.sterimaxinc.com
E-mail: kandrus@sterimaxinc.com

FEIN: 61-2338290
State of Formation: Delaware
Date Incorporated: 3/10/2026
File Number: 10537512

Ownership Information

SteriMax USA Inc. is 100% owned by SteriMax Inc.
Parent Company Address: 2770 Portland Dr. Oakville, Ontario Canada L6H 6R4
Parent Company Phone: 905-890-0661
Parent Company FEIN: 61-2338290

Officers

Ed Rajasigham, Chief Commercial Officer
Business Address: 2770 Portland Drive Oakville, Ontario Canada L6H 6R4
Business Phone: 365-228-1479
Email: erajasigham@sterimaxinc.com

Samir Acharya, President & CEO
Business Address: 2770 Portland Drive Oakville, Ontario Canada L6H 6R4
Business Phone: 365-228-1479
Email: sacharya@sterimaxinc.com

Ritesh Acharya, Chief Scientific Officer
Business Address: 2770 Portland Dr Oakville, Ontario Canada L6H 6R4
Business Phone: 365-228-1479
Email: RAcharya@Sterimaxinc.com

Scott Niewland, CFO
Business Address: 2770 Portland Dr Oakville, Ontario Canada L6H 6R4
Business Phone: 365-228-1479
Email: sniewland@sterimaxinc.com

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "STERIMAX USA INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SIXTH DAY OF MAY, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL FRANCHISE TAXES HAVE BEEN ASSESSED TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

10537512 8300

SR# 20262330022

Authentication: 203859451

Date: 05-06-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0027410

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written noticeprior to the change of the address of such new location and the name and address of the individual to be in charge thereof.A fee of $20.00 shall accompanying such notification."

Registered as: ☑ Manufacturer ☑ Distributor which conducts business at the following locations:

Reg. No.:
7203385

STERIMAX USA INC
1136 HIGHWAY 22
MOUNTAINSIDE, NJ 07092

ISSUED PURSUANT TO:
N.J.S.A. 24:6B
EXPIRES: January 31, 2027

Establishment Copy

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. ACC021001292

Application/License No. _____

SteriMax USA Inc., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
1136 US Highway 22, Mountainside, NJ 07092, as
(Address of Applicant/Principal)
PRINCIPAL, and Allegheny Casualty Company, a
(Surety Company)
corporation organized under the laws of the state of New Jersey
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
One Newark Center, 20th Floor, Newark, NJ 07102 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on June 9, 2026.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 9th day of June, 2026.

APPLICANT/PRINCIPAL

COMPANY SteriMax USA Inc.

Authorized Representative

SURETY

Allegheny Casualty Company

Surety Company's Representative

Hillary D. Shepard, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Ellen Zhang

Witness SIMA ACHARYA

SIGNED and SEALED in the presence of:

Witness Erin C. Lavin

Witness Amy S. Fulton

Countersigned by:

N/A
Nevada Resident Agent

Deborah Susan Rotim
Notary Public, Province of Ontario
Limited to the attestation of instruments and the taking of affidavits for SteriMax Inc.
Expires November 1, 2026

allegheny
CASUALTY COMPANY
One Newark Center, 20th. Floor, Newark, New Jersey, 07102-5207
PHONE: (973) 624-7200

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That **ALLEGHENY CASUALTY COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, having its principal office in the City of Newark, New Jersey, does hereby constitute and appoint

Marina Tapia, Rachel A Mullen, KD Wapato, Abigail E Curtiss, Debra J Scarborough, Christy M Braile, Teresa D Kelly, Caitlyn Magennis, Lourdes Scheel, Hillary D Shepard, Sandra Corona, Maegen Allhands, Walker Wilks, Ivette Bustos, Chase Seyforth, Robert F. Laing, Veronica Lawver

its true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **ALLEGHENY CASUALTY COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by its regularly elected officers at its principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **ALLEGHENY CASUALTY COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **ALLEGHENY CASUALTY COMPANY** at a meeting duly held on the 13th day of December, 2018.

"RESOLVED, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-Fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **ALLEGHENY CASUALTY COMPANY** has executed and attested these presents on this 31st day of December 2021

ALLEGHENY CASUALTY COMPANY CORPORATE SEAL 1936 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

Robert Kerstrick
Vice President, ALLEGHENY CASUALTY COMPANY

On this 31st day of December, 2021, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of ALLEGHENY CASUALTY COMPANY; that the seal affixed to said instrument is the Corporate Seal of said Company; that the said Corporate Seal and his signature were duly affixed by order of the Boards of Directors of said Company.

Michele A. Aleman NOTARY PUBLIC MY COMMISSION EXPIRES 10-18-2023 NOTARY PUBLIC STATE OF NEW JERSEY

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written

Michele A Aleman, a Notary Public of New Jersey

CERTIFICATION

I, the undersigned officer of **ALLEGHENY CASUALTY COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Company as set forth in said Power of Attorney, with the originals on file in the home office of said company, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this 9th day of June, 2026

James Portman, Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler SteriMax USA Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 1136 Highway 22

City Mountainside State NJ Zip 07092

Mailing Address (if different from physical address) 1136 Highway 22

City Mountainside State New Jersey Zip 07092

Telephone 877-373-4657 Website https://sterimaxinc.com

Licensing Company Email kandrus@sterimaxinc.com

Section 2: Personal Information

First Karen Middle Susan Last Andrus

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 1136 Highway 22

City Mountainside State New Jersey Zip 07092

Telephone 877-373-4657 Email kandrus@sterimaxinc.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	NA	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Tulane University		08/81- 05/85	
Address	**City**	**State**	**Zip**
6823 Saint Charles Ave	New Orleans	LA	70118
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Jonathan Dayton Regional High School		1977-1981	
Address	**City**	**State**	**Zip**
	Springfield	NJ	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/04- Present	[redacted]	Mountainside	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
SteriMax USA Inc.			01/26- Present
Business Address	**City**	**State**	**Zip**
1136 Highway 22	Mountainside	NJ	07092
Phone	**Title**	**Number of Employed Hours**	
877-373-4657	Head, US Business	920	

Description of Duties

See attached resume.

Business Name			From - To (MM/YY – MM/YY)
Wockhardt USA			07/23 – 04/25
Business Address	**City**	**State**	**Zip**
20 Waterview Blvd. #3	Parsippany	NJ	07054
Phone	**Title**	**Number of Employed Hours**	
	Vice President, Pricing & Contracts	3800	

Description of Duties

See attached resume.

Business Name			From - To (MM/YY – MM/YY)
Provepharm, Inc.			02/19- 06/23
Business Address	**City**	**State**	**Zip**
100 Springhouse Drive, Suite 105	Collegeville	PA	19426
Phone	**Title**	**Number of Employed Hours**	
	Executive Director	7640	

Description of Duties

See attached resume.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Karen Andrus

Mountainside, New Jersey, United States

[redacted]

Summary

Objective

Leverage my extensive experience in pharmaceutical commercial contracting, operations, and sales with an entrepreneurial organization in a customer facing role. I have a proven track record of building and developing teams to support a rapidly expanding business model. Teamwork, collaboration, and business ethics are stressed in the development of processes and culture.

Experience

Head, US Business

Sterimax USA Inc.

January 2026 – Present

Establish US office and secure state licenses and distribution agreements for first product launch.

Vice President, Pricing & Contracts

Wockhardt USA

Jul 2023 – April 2025

Strategic pricing utilizing competitive information with Gross-to-Net profitability analysis on all new sales opportunities and market price changes

Negotiate terms and conditions of agreements on generic product line of oral solids, injectables and liquids with GPO, chains, mail order, and wholesaler customers

Process and approve all commercial customers' administrative fees and rebate programs

Coordinate product launch activities

Executive Director

Provepharm, Inc.

Apollo USA Inc.

Feb 2019 – Jul 2023 (4 years 4 months)

Establish company as a New Vendor/Supplier at wholesalers and GPOs for both the generic line and brand line of products

Successfully negotiate both generic and brand portfolio's Master Services Agreements with national and regional wholesalers in addition to Wholesaler Generic Source Programs and institutional GPOs such as Vizient, HPG, and Premier

Managed the launch process of Apollo USA's first three products in its initial year and developed and coordinated all NDC conversions to Provepharm label

Account Responsibilities with Trade Relations/Wholesalers

Subject Matter Expert on chargebacks, commercial rebates, sales reporting

Identified, evaluated, and selection a revenue management system and managed services for government reporting and Medicaid rebates.

Responsible for coordinating with Finance and Supply Chain on accruals and coordination of product availability

Developed model and process for profitability analysis on all new business opportunities and price adjustments
Coordinate activities at our third-party logistics company in fulfilling customer orders
Manage commercial support staff, including bid preparation, award implementation, rebate processing, and state licensing
Develop and execute monthly and ad hoc reporting and analysis of IQVIA market share data
Held accountable for sales targets and achievements

Senior Director, Sales
Viona Pharmaceuticals Inc.
Nov 2018 – February 2019 (3 months)
Cultivate and maintain high-value customer relationships to establish loyalty and build trust with key customer decision makers
Develop generic product pricing strategy and implement process through organization
Effectively Negotiate contract terms with wholesalers, chains, mail order, and GPOs
Develop sales and expense budget for the sales department and monitor
Achieve budgeted sales, maintain, and increase sales of company's products
Participate in trade shows and travel to customer meetings on a regular basis for business reviews and future opportunities
Create and regularly update business plans

Senior Director, Sales
Wockhardt USA
Oct 2008 - Nov 2018 (10 years 2 months)
Strategic pricing utilizing competitive information with Gross-to-Net profitability analysis on all new sales opportunities and market price changes
Negotiate terms and conditions of agreements on generic product line of oral solids, injectables, liquids and OTC products with GPO, chains, mail order, and wholesaler customers
Managed all internal sales operations including Customer Service, Bid & Contracts, and Rebates departments
Coordinate bi-weekly field sales conference call with product launch and supply updates
Developed and implemented competitive and bid tracking databases
Prepare and maintain all upcoming launch information and product information for the field force
Participate as a Steering Committee member in brand marketing efforts providing government pricing policies information and reimbursement practices
Developed and implemented automated SAP accrual process for rebates, promotions, and chargebacks
Recruit and train new department personnel for NJ office growth
Consolidated contract management solution for Morton Grove and Wockhardt USA product lines
Sales calls to key accounts and industry trade show and conferences
Develop and implement product promotions
Implement and coordinate all price increases and product discontinuations
Set AWP, WAC, and contract pricing on product launches and create offers
SME in Vistex implementation for revenue management

Senior Director
DAVA Pharmaceuticals, Inc.
Aug 2006 - Sep 2008 (2 years 2 months)

Assist the Senior VP Sales & Operations with developing and implementing strategies to gain market share on existing products and new product launches
Develop and implement product promotions
Manage bids and awards on both generic and brand products in both commercial and federal markets
Primary pricing decision maker on almost 100 contracts and 130 skus
Develop account specific pricing and produce all new product launch offers, including generics of Omnicef, Rheumatrex, Kytril, Sonata, and Vospire
Field sales representative for all Institutional GPO business
Implement all market-wide price increases and reductions
Process and approve quarterly rebates and administrative fees
Participate in industry trade shows and conferences on a regular basis

Director, Contract Management
Par Pharmaceutical
Jan 1998 - Aug 2006 (8 years 8 months)
Manage bids and awards on both generic and brand products in both commercial and federal markets
Pricing decisions on over 100 contracts and 400 skus
Develop account specific pricing and produce all new product launch offers, including generics of Prozac, Megace OS, Paxil, and Flonase
Field sales representative for all Institutional GPO business
Implement all market-wide price increases and reductions
Process and approve quarterly rebates and administrative fees
Participate in industry trade shows and conferences on a regular basis
Implemented new contract pricing system
Key contributor to company's dramatic sales growth since 1988

Manager, Customer Care
Health Plans, Inc.
Jan 1996 - Jan 1998 (2 years 1 month)

Manager, Bids & Contracts
Zenith Laboratories Inc
Jan 1992 - Jan 1996 (4 years 1 month)
of all discount prescription card accounts
Managed and coordinated bids submissions and contract implantation of generic pharmaceuticals
Pricing analysis and contract performance reporting with an emphasis on managed care
Developed pull-through programs and rebate structures
Field account responsibilities including AARP, MHA, and PruCare
Accompanied Regional Sales Mgr/Directors on sales calls

Assistant Manager, Government & Institutional Aales
Ciba-Geigy
Jan 1988 - Jan 1992 (4 years 1 month)
Analyzed and competitively price all institutional bids

Supervised and train staff of six bid coordinators
Organized customer notifications of all price changes and product launches
Developed and implemented several systems to track and analyze bid performance

Education

Tulane University 1981-1985
Bachelor of Science

Skills

Analytical Skills • Teamwork • Decision-Making • Tenacious Work Ethic • Organization Skills • Leadership • Communication • Contract Management • Contract Negotiation • Commercial

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Karen Andrus, **certify that as the designated representative for**

SteriMax USA Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. KA I am at least 21 years of age;
3. KA I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. KA I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. KA I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. KA I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. KA I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Karen Andrus
Print Name (First, Last)

Karen Andrus
Original Signature (electronic, copies or stamps not accepted)

7/8/26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Karen Andrus

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) — Date: 7/10/26

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Union

I, Karen Andrus, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature — **Date:** 7/10/26

Subscribed and Sworn to before me this 10th day of July 2026

Notary Public Signature

ROBERTO J RODRIGUEZ
Notary Public
State of New Jersey
My Commission Expires Dec. 4, 2028
I.D.# 50216260

(Seal)

STERIMAX

U.S. Employee List

Karen Andrus, Head, US Business

4EE

*Application is for Change of Ownership at Grandparent Level and Change of Address. Please see attached flash. VDS-EHR-NV

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☒ Ownership Change*- Grandparent ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH [illegible]02433	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Validus Pharmaceuticals LLC

Physical Address: 40F Cotters Lane, Suite A

City: East Brunswick State: NJ Zip: 08816

Mailing Address (if different from physical address): c/o State License Servicing, Inc., 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: validuspharma.com

Name of Designated Representative (DR): Emile Awadagin Williams

Licensing Company Email: VDS@slsny.com DR Email: ewilliams@validuspharma.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☒ Others: Manufacturer - Virtual

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A - None to disclose.

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Cencora
Address: 1 West First Avenue City: Conshohocken State: PA Zip: 19428
Name: Cardinal Health
Address: 7000 Cardinal Pl City: Dublin State: OH Zip: 43017
Name: Mckesson
Address: 6555 State Highway 161 City: Irving State: TX Zip: 75039
Name:
Address: City: State: Zip:

N/A **Section 4: Publicly Traded Corporation**

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): AdvaGen Holdings Inc. (100%)
Corporation/Organization Name: Validus Pharmaceuticals LLC
Mailing Address: c/o State License Servicing, Inc., 225 Dolson Ave., 4th floor
City: Middletown State: NY Zip: 10940
Telephone: (845) 544-2482 Email: VDS@slsny.com
Contact Person Name: Christine Cannon

N/A **Section 6: Partnership**

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

N/A **Section 7: Sole Owner**

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: NDC Labeler Code: 30698	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Validus Pharmaceuticals LLC

Facility Name

Eric Robert Schumacher

Print Name of Authorized Person Submitting Application

ERS

Original signature of Authorized Person (copies or stamps not accepted)

7/29/2026

Date

Board Use Only	Date Received: 9/10/26	Amount: $1000 CK 5682

Proof of NDC Labeler Code

/ NDC (index.cfm)

National Drug Code Directory

Current through September 02, 2026

You have searched Finished drug products

Search Results: '30698'

Back to Search Page () | Search Again ()

CSV Excel

Display 50 records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
ATONCY	30698-456-02	4 mg/mL	SOLUTION	ORAL	NDA220320	Validus Pharmaceuticals LLC	30698-456	Atomoxetine hydrochloride	ATOMOXETINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	03/20/2026	N/A	NDA	1 BOTTLE, GLASS in 1 CARTON (30698-456-02) / 100 mL in 1 BOTTLE, GLASS
Bumex	30698-630-01	5 mg/1	TABLET	ORAL	NDA018225	Validus Pharmaceuticals LLC	30698-630	Bumetanide	BUMETANIDE	HUMAN PRESCRIPTION DRUG	02/28/1983	N/A	NDA	100 TABLET in 1 BOTTLE (30698-630-01)
Bumex	30698-631-01	1 mg/1	TABLET	ORAL	NDA018225	Validus Pharmaceuticals LLC	30698-631	Bumetanide	BUMETANIDE	HUMAN PRESCRIPTION DRUG	02/28/1983	N/A	NDA	100 TABLET in 1 BOTTLE (30698-631-01)
Bumex	30698-631-05	1 mg/1	TABLET	ORAL	NDA018225	Validus Pharmaceuticals LLC	30698-631	Bumetanide	BUMETANIDE	HUMAN PRESCRIPTION DRUG	01/17/2024	N/A	NDA	500 TABLET in 1 BOTTLE (30698-631-05)
Bumex	30698-632-01	2 mg/1	TABLET	ORAL	NDA018225	Validus Pharmaceuticals LLC	30698-632	Bumetanide	BUMETANIDE	HUMAN PRESCRIPTION DRUG	02/28/1983	N/A	NDA	100 TABLET in 1 BOTTLE (30698-632-01)
Bumex	30698-632-05	2 mg/1	TABLET	ORAL	NDA018225	Validus Pharmaceuticals LLC	30698-632	Bumetanide	BUMETANIDE	HUMAN PRESCRIPTION DRUG	01/17/2024	N/A	NDA	500 TABLET in 1 BOTTLE (30698-632-05)
EQUETRO	30698-419-12	100 mg/1	CAPSULE, EXTENDED RELEASE	ORAL	NDA021710	Validus Pharmaceuticals LLC	30698-419	Carbamazepine	CARBAMAZEPINE	HUMAN PRESCRIPTION DRUG	12/10/2004	N/A	NDA	120 CAPSULE, EXTENDED RELEASE in 1 BOTTLE (30698-419-12)
EQUETRO	30698-421-12	200 mg/1	CAPSULE, EXTENDED RELEASE	ORAL	NDA021710	Validus Pharmaceuticals LLC	30698-421	Carbamazepine	CARBAMAZEPINE	HUMAN PRESCRIPTION DRUG	12/10/2004	N/A	NDA	120 CAPSULE, EXTENDED RELEASE in 1 BOTTLE (30698-421-12)
EQUETRO	30698-423-12	300 mg/1	CAPSULE, EXTENDED RELEASE	ORAL	NDA021710	Validus Pharmaceuticals LLC	30698-423	Carbamazepine	CARBAMAZEPINE	HUMAN PRESCRIPTION DRUG	12/10/2004	N/A	NDA	120 CAPSULE, EXTENDED RELEASE in 1 BOTTLE (30698-423-12)
Lasix	30698-060-01	40 mg/1	TABLET	ORAL	NDA016273	Validus Pharmaceuticals LLC	30698-060	FUROSEMIDE	FUROSEMIDE	HUMAN PRESCRIPTION DRUG	04/24/1978	N/A	NDA	100 TABLET in 1 BOTTLE (30698-060-01)
Lasix	30698-060-10	40 mg/1	TABLET	ORAL	NDA016273	Validus Pharmaceuticals LLC	30698-060	FUROSEMIDE	FUROSEMIDE	HUMAN PRESCRIPTION DRUG	04/24/1978	N/A	NDA	1000 TABLET in 1 BOTTLE (30698-060-10)
Lasix	30698-060-50	40 mg/1	TABLET	ORAL	NDA016273	Validus Pharmaceuticals LLC	30698-060	FUROSEMIDE	FUROSEMIDE	HUMAN PRESCRIPTION DRUG	04/24/1978	N/A	NDA	500 TABLET in 1 BOTTLE (30698-060-50)

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
Lasix	30698-066-05	80 mg/1	TABLET	ORAL	NDA016273	Validus Pharmaceuticals LLC	30698-066	FUROSEMIDE	FUROSEMIDE	HUMAN PRESCRIPTION DRUG	04/24/1978	N/A	NDA	50 TABLET in 1 BOTTLE (30698-066-05)
Lasix	30698-066-50	80 mg/1	TABLET	ORAL	NDA016273	Validus Pharmaceuticals LLC	30698-066	FUROSEMIDE	FUROSEMIDE	HUMAN PRESCRIPTION DRUG	04/24/1978	N/A	NDA	500 TABLET in 1 BOTTLE (30698-066-50)
Lasix	30698-067-01	20 mg/1	TABLET	ORAL	NDA016273	Validus Pharmaceuticals LLC	30698-067	FUROSEMIDE	FUROSEMIDE	HUMAN PRESCRIPTION DRUG	04/24/1978	N/A	NDA	100 TABLET in 1 BOTTLE (30698-067-01)
Lasix	30698-067-10	20 mg/1	TABLET	ORAL	NDA016273	Validus Pharmaceuticals LLC	30698-067	FUROSEMIDE	FUROSEMIDE	HUMAN PRESCRIPTION DRUG	04/24/1978	N/A	NDA	1000 TABLET in 1 BOTTLE (30698-067-10)
Lopressor	30698-458-01	50 mg/1	TABLET	ORAL	NDA017963	Validus Pharmaceuticals LLC	30698-458	metoprolol tartrate	METOPROLOL TARTRATE	HUMAN PRESCRIPTION DRUG	05/05/2014	N/A	NDA	100 TABLET in 1 BOTTLE (30698-458-01)
Lopressor	30698-459-01	100 mg/1	TABLET	ORAL	NDA017963	Validus Pharmaceuticals LLC	30698-459	metoprolol tartrate	METOPROLOL TARTRATE	HUMAN PRESCRIPTION DRUG	05/05/2014	N/A	NDA	100 TABLET in 1 BOTTLE (30698-459-01)
LOPRESSOR	30698-460-03	12.5 mg/1	TABLET	ORAL	NDA218698	VALIDUS PHARMACEUTICALS LLC	30698-460	METOPROLOL TARTRATE	METOPROLOL TARTRATE	HUMAN PRESCRIPTION DRUG	08/11/2025	N/A	NDA	30 TABLET in 1 BOTTLE (30698-460-03)
LOPRESSOR	30698-460-10	12.5 mg/1	TABLET	ORAL	NDA218698	VALIDUS PHARMACEUTICALS LLC	30698-460	METOPROLOL TARTRATE	METOPROLOL TARTRATE	HUMAN PRESCRIPTION DRUG	08/11/2025	N/A	NDA	1000 TABLET in 1 BOTTLE (30698-460-10)
LOPRESSOR	30698-460-01	12.5 mg/1	TABLET	ORAL	NDA218698	VALIDUS PHARMACEUTICALS LLC	30698-460	METOPROLOL TARTRATE	METOPROLOL TARTRATE	HUMAN PRESCRIPTION DRUG	01/25/2026	N/A	NDA	60 TABLET in 1 BOTTLE (30698-460-01)
LOPRESSOR	30698-464-31	10 mg/mL	SOLUTION	ORAL	NDA219373	VALIDUS PHARMACEUTICALS LLC	30698-464	Metoprolol Tartrate	METOPROLOL TARTRATE	HUMAN PRESCRIPTION DRUG	04/11/2025	N/A	NDA	1 BOTTLE in 1 CARTON (30698-464-31) / 300 mL in 1 BOTTLE
LOPRESSOR	30698-464-30	10 mg/mL	SOLUTION	ORAL	NDA219373	VALIDUS PHARMACEUTICALS LLC	30698-464	Metoprolol Tartrate	METOPROLOL TARTRATE	HUMAN PRESCRIPTION DRUG	04/11/2025	N/A	NDA	1 BOTTLE in 1 CARTON (30698-464-30) / 300 mL in 1 BOTTLE
Lotensin	30698-448-01	10 mg/1	TABLET	ORAL	NDA019851	Validus Pharmaceuticals LLC	30698-448	benazepril hydrochloride	BENAZEPRIL HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	06/21/1991	N/A	NDA	100 TABLET in 1 BOTTLE (30698-448-01)
Lotensin	30698-449-01	20 mg/1	TABLET	ORAL	NDA019851	Validus Pharmaceuticals LLC	30698-449	benazepril hydrochloride	BENAZEPRIL HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	06/21/1991	N/A	NDA	100 TABLET in 1 BOTTLE (30698-449-01)
Lotensin	30698-450-01	40 mg/1	TABLET	ORAL	NDA019851	Validus Pharmaceuticals LLC	30698-450	benazepril hydrochloride	BENAZEPRIL HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	06/21/1991	N/A	NDA	100 TABLET in 1 BOTTLE (30698-450-01)
Lotensin HCT	30698-452-01	10 mg/1; 12.5 mg/1	TABLET	ORAL	NDA020033	Validus Pharmaceuticals LLC	30698-452	benazepril hydrochloride and hydrochlorothiazide	BENAZEPRIL HYDROCHLORIDE; HYDROCHLOROTHIAZIDE	HUMAN PRESCRIPTION DRUG	05/30/1992	N/A	NDA	100 TABLET in 1 BOTTLE (30698-452-01)
Lotensin HCT	30698-453-01	20 mg/1; 12.5 mg/1	TABLET	ORAL	NDA020033	Validus Pharmaceuticals LLC	30698-453	benazepril hydrochloride and hydrochlorothiazide	BENAZEPRIL HYDROCHLORIDE; HYDROCHLOROTHIAZIDE	HUMAN PRESCRIPTION DRUG	05/30/1992	N/A	NDA	100 TABLET in 1 BOTTLE (30698-453-01)
Lotensin HCT	30698-454-01	20 mg/1; 25 mg/1	TABLET	ORAL	NDA020033	Validus Pharmaceuticals LLC	30698-454	benazepril hydrochloride and hydrochlorothiazide	BENAZEPRIL HYDROCHLORIDE; HYDROCHLOROTHIAZIDE	HUMAN PRESCRIPTION DRUG	05/30/1992	N/A	NDA	100 TABLET in 1 BOTTLE (30698-454-01)
Norpramin	30698-007-01	10 mg/1	TABLET, SUGAR COATED	ORAL	NDA014399	Validus Pharmaceuticals LLC	30698-007	desipramine hydrochloride	DESIPRAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/20/1964	N/A	NDA	100 TABLET, SUGAR COATED in 1 BOTTLE (30698-007-01)

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
Norpramin	30698-011-01	25 mg/1	TABLET, SUGAR COATED	ORAL	NDA014399	Validus Pharmaceuticals LLC	30698-011	desipramine hydrochloride	DESIPRAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/20/1964	N/A	NDA	100 TABLET, SUGAR COATED in 1 BOTTLE (30698-011-01)
Norpramin	30698-015-01	50 mg/1	TABLET, SUGAR COATED	ORAL	NDA014399	Validus Pharmaceuticals LLC	30698-015	desipramine hydrochloride	DESIPRAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/20/1964	N/A	NDA	100 TABLET, SUGAR COATED in 1 BOTTLE (30698-015-01)
Norpramin	30698-019-01	75 mg/1	TABLET, SUGAR COATED	ORAL	NDA014399	Validus Pharmaceuticals LLC	30698-019	desipramine hydrochloride	DESIPRAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/20/1964	N/A	NDA	100 TABLET, SUGAR COATED in 1 BOTTLE (30698-019-01)
Norpramin	30698-020-01	100 mg/1	TABLET, SUGAR COATED	ORAL	NDA014399	Validus Pharmaceuticals LLC	30698-020	desipramine hydrochloride	DESIPRAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/20/1964	N/A	NDA	100 TABLET, SUGAR COATED in 1 BOTTLE (30698-020-01)
Norpramin	30698-021-50	150 mg/1	TABLET, SUGAR COATED	ORAL	NDA014399	Validus Pharmaceuticals LLC	30698-021	desipramine hydrochloride	DESIPRAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/20/1964	N/A	NDA	50 TABLET, SUGAR COATED in 1 BOTTLE (30698-021-50)
RALDESY	30698-455-01	10 mg/mL	SOLUTION	ORAL	NDA218637	Validus Pharmaceuticals LLC	30698-455	TRAZODONE HYDROCHLORIDE ORAL	TRAZODONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/26/2024	N/A	NDA	300 mL in 1 BOTTLE (30698-455-01)
RALDESY	30698-455-02	10 mg/mL	SOLUTION	ORAL	NDA218637	Validus Pharmaceuticals LLC	30698-455	TRAZODONE HYDROCHLORIDE ORAL	TRAZODONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/26/2024	N/A	NDA	150 mL in 1 BOTTLE (30698-455-02)

Showing 1 to 37 of 37 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Pre + Post Org Chart

40F Cotters Lane
Suite A
East Brunswick NJ 08816
973-265-2777 Main

POST ORGANIZATIONAL CHART

Rubicon Research LTD

MedOne House Plot No. B-75,Road No. 33, Wagle Estate

Thane West, India 400604

NO FEIN: FOREIGN ENTITY

100%

AdvaGen Holdings Inc.

50 Milestone Road, Building 200, 1st Floor, Suite 180 East Windsor, NJ 08520

FEIN: 87-1593998

100%

Validus Pharmaceuticals LLC

40F Cotters Lane, Suite A,

East Brunswick, NJ 08816

FEIN: 20-8870855

Validus
PHARMACEUTICALS
973-265-2777 Main

90 East Halsey Rd
Suite 210
Parsippany, NJ 07054

PRE ORGANIZATIONAL CHART

Rubicon Research Private LTD

MedOne House Plot No. B-75,Road No. 33, Wagle Estate
Thane West, India 400604

NO FEIN: FOREIGN ENTITY

100%

AdvaGen Holdings Inc.

50 Milestone Road, Building 200, 1st Floor, Suite 180
East Windsor, NJ 08520

FEIN: 87-1593998

100%

Validus Pharmaceuticals LLC

90 E Halsey Rd Ste. 210
Parsippany, NJ 07054

FEIN: 20-8870855

Officer List

Validus
PHARMACEUTICALS LLC

40F Cotters Lane, Suite A
East Brunswick, NJ 08816
validuspharma.com

CERTIFICATE OF INCUMBENCY

VALIDUS PHARMACEUTICAL LLC

I, Narendra N. Borkar, President of Validus Pharmaceutical LLC (the "Company") a limited liability company organized and existing under the laws of the State of Delaware, hereby certify that as of the date hereof, the following individuals are the duly elected or appointed officers of the Company, holding the positions set forth below, effective February 3, 2026:

Officers:

Narendra N. Borkar	President
Eric Robert Schumacher	Executive Vice President

This Certificate is being issued to confirm the officers of Validus Pharmaceutical LLC as of March 27, 2026.

IN AS WITNESS WHEREOF, I have hereunto set my hand as of March 27, 2026.

Narendra N. Borkar
President

Validus Pharmaceuticals LLC

Corporate Address: 40F Cotters Lane, Suite A, East Brunswick, NJ 08816 USA
FEIN: 20-8870855
validuspharma.com

Drug Labeler Code: 30698
Incorporation State: DE
Incorporation Date: 04/19/2007

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
COT	40F Cotters Lane Suite A East Brunswick, NJ 08816 County:	N/A	N/A - No CS	801194619	No	(973) 265-2777	N/A

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Emile Awadagin Williams	[redacted]	Chief Operating Officer	No	[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
AdvaGen Holdings Inc.	50 Milestone Road Building 200, 1st Floor, Suite 180 East Windsor, NJ 08520	N/A	100%	N/A	87-1593998	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Narendra Narhar Borkar	[redacted]	President	No	[redacted]		
Eric Robert Schumacher		Executive Vice President	No			

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
InCorp Services			

3PLS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
AIM Rx3PL, LLC	40F Cotters Lane Suite 100 East Brunswick, NJ 08816					

Company Partnerships

Flash Notice for Grandparent CHOW, Address + officer change

From: compliance@slsnysupport.com
Subject: Notice of Change of Address // Change of Grandparent Name // Change of Officer; Licenses in the name of: Validus Pharmaceuticals LLC
Date: July 24, 2026 at 3:26 PM
To: pharmacy@pharmacy.nv.gov

IMPORTANT NOTICE

Date: July 24, 2026
To: Nevada State Board of Pharmacy
Re: Validus Pharmaceuticals LLC, 90 E. Halsey Rd. , Ste. 210, Parsippany, NJ 07054, Permit #: WH02933

Dear Licensing Authority:

State License Servicing, Inc. represents *Validus Pharmaceuticals LLC,* a Delaware limited liability company, in the servicing of its state licenses. This letter shall serve as notice of some changes *Validus Pharmaceuticals LLC* is undergoing. All changes are listed below:

Change of Facility Address: On or about August 1, 2026 , the new facility address will be as follows:
40F Cotters Lane, Suite A
East Brunswick, NJ 08816

Change of Grandparent Name:
Effective July 24, 2024, Rubicon Research Private Ltd converted into a Public entity and changed their name.

- ***Former Name***: Rubicon Research Private Ltd
- ***New Name***: Rubicon Research Limited (publicly traded)

Change of Officer:
Effective February 3, 2026, the new officers of *Validus Pharamceuticals LLC* will be Narendra Borkar as President and Eric Schumacher as Executive Vice President.

- **Name:** Narendra Borkar, President
- **Business Address:** 40F Cotters Lane, Suite A, East Brunswick, NJ 08816
- **Ownership %:** 0%
- **Email:** narendra.borkar@advagenpharma.com **Work #:** 609-269-8128

- **Name:** Eric Schumacher, Executive Vice President
- **Business Address:** 40F Cotters Lane, Suite A, East Brunswick, NJ 08816
- **Ownership %:** 0%
- **Email:** eric.schumacher@advagenpharma.com **Work #:** 609- 269-8128

To confirm, the revised officer list for *Validus Pharmaceuticals LLC* will be:
- **Narendra N. Borkar** - President
- **Eric R. Schumacher** – Executive Vice President

Please be assured that if your state requires any additional forms, filings and associated fees to effectuate this change, these will be completed and will be filed appropriately. If you need any additional information, please feel free to email me at the address below.

Kind regards,

Christine Cannon
Chief Production Officer
State License Servicing, Inc.
VDS@slsny.com

THIS ELECTRONIC MAIL MESSAGE AND ANY ATTACHMENT IS CONFIDENTIAL AND MAY CONTAIN LEGALLY PRIVILEGED INFORMATION INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR INDIVIDUALS NAMED ABOVE.

Click Here to Respond to this Email

*Good Standing

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "VALIDUS PHARMACEUTICALS LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF MAY, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "VALIDUS PHARMACEUTICALS LLC" WAS FORMED ON THE NINETEENTH DAY OF APRIL, A.D. 2007.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 204022525

Date: 05-23-26

4337564 8300

SR# 20262815502

You may verify this certificate online at corp.delaware.gov/authver.shtml

Home State (NJ) Verification of License

Registration Number: 7603872 **Registered As:** Manufacturer

Information Recorded in the System as of 09/02/2026

Name: Validus Pharmaceuticals LLC

New Jersey Department of Health

DBA:

Address: 40 F Cotters LN STE A EAST BRUNSWICK, NJ 08816

Original Issue Date: 08/31/2027 **Expiration Date:** 01/31/2027

Current Issue Date: 08/31/2026

Disciplines: No

Permit Status: Active

• Change supersedes and replaces any and all 10BSBIL5748 previously issued.

THE HARTFORD

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Suite 206
Reno, NV 89521

RIDER

Attached to and forming part of Bond # 10BSBIL5748 ,
on behalf of Validus Pharmaceuticals LLC
of 90 East Halsey Rd, Suite 210, Parsippany, NJ 07054
in favor of Nevada State Board of Pharmacy
and in the amount of Twenty-Five Thousand ($25,000.00) Dollars.

It is understood and agreed that effective 08/01/2026
The Principal Address shall be changed and billing
from 90 East Halsey Rd, Suite 210 Parsippany NJ 07054
to 40 Cotters Ln Ste F East Brunswick NJ 08816

All other conditions and terms re main as originally written.

Signed, Sealed, and Dated July, 30th , 2026

Hartford Fire Insurance Company

By: _____
Joelle L LaPierre , Attorney-in-Fact

The above rider is hereby agreed to and accepted:

By: _____

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: USI INSURANCE SERVICES LLC
Agency Code: 10-257143

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Joelle L LaPierre
of Lake Mary, Florida,
its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by, and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 10BSBI15748
Naming Validus PharmaceuLicals LLC as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 30th day of March, 2026, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone
My Commission HH 644184
Expires June 20, 2029

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of July 30, 2026.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

THE HARTFORD

Verification Certificate

This is to certify that Bond No. 10 BSBIL5748 issued by the member company of The Hartford subscribing this certificate, dated October 15, 2026

in the amount of Twenty-Five Thousand Dollars

$25,000.00

on behalf of Validus Pharmaceuticals LLC , as Principal,

and in favor of Nevada State Board of Pharmacy , as Obligee,

covers an indefinite term which began on October 15, 2021 , and ends with the cancellation of said bond; that said bond is now in full force and effect and will continue in full force and effect until cancelled.

ANNIVERSARY PREMIUM PERIOD: October 15, 2026 to October 15, 2027

Signed, Sealed, and Dated July 29, 2026

Attest or Witness

Shelby Wiggins

Surety

Hartford Fire Insurance Company

By: Joelle L LaPierre, Attorney in fact

HARTFORD FIRE INSURANCE CO. INCORPORATED 1810

1030-E-1

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: USI INSURANCE SERVICES LLC
Agency Code: 10-257143

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Joelle L LaPierre
of Lake Mary, Florida,
its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by, and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 10BSBIL5748
Naming Validus Pharmaceuticals LLC as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 30th day of March, 2026, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone
My Commission HH 644184
Expires June 20, 2029

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of July 30, 2026.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

Revised: March 31, 2026

Bond Continuance

USI Insurance Services LLC

P.O. Box 62939 * Virginia Beach, VA 23466

---------- INVOICE ----------

Validus Pharmaceuticals, LLC
40 Cotters Ln Ste A
Suite 210
East Brunswick, NJ 08816-2043

Named Insured: Validus Pharmaceuticals, LLC

Invoice Date	08/03/26
Invoice No.	6095867
Bill-To Code	VALIDPHA
Client Code	VALIDPHA
Inv Order No.	777*8884202

Amount Remitted: $
Pay via Credit Card or EFT Draft: usi.com/paymybill

Make checks payable to: USI Insurance Services LLC

Effective Date	Policy Period	Coverage Description	Transaction Amount
10/15/26	10/15/26 to 10/15/27	Hartford Fire Insurance Company Policy No. 10BSBIL5748 *New - Miscellaneous Bond	250.00
		$25,000 - Nevada State Board of Pharmacy - Pharmaceutical Wholesaler Bond	
		Invoice Number: 6095867 Amount Due:	250.00

***Premiums Due and Payable on Effective Date**

FRAUD PREVENTION NOTICE: USI will never provide unsolicited payment instructions. You should only change payment instructions if confirmed by calling your USI Account Manager or contacting your local USI office.

JXQC2 Page: 1 ORIGINAL INVOICE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Validus Pharmaceuticals LLC

Pharmacy/Wholesaler License # (if applicable): WH02933

Physical Address: 40 Cotters Lane, Suite A

City: East Brunswick State: NJ Zip: 08816

Mailing Address (if different from physical address): c/o State License Servicing, Inc. 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: validuspharma.com

Licensing Company Email: VDS@slsny.com

Section 2: Personal Information

First: Preethy Middle: Louise Last: Rego

Alias(es, nicknames, name changes, etc.): NONE

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: Plainsboro State: NJ Zip: [redacted]

Telephone: [redacted] Email: preethy.rego@validuspharma.com

Are you a citizen of the United States? ☐ Yes ■ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
IBMS Chittoor University		2004 - 2005	
Address	**City**	**State**	**Zip**
Johns Garden, Palamaner Road, Chittoor - 517002	Andhra Pradesh, India		
Diploma/Degree obtained, if any			
Post Graduate Diploma in Psychological Counselling			

School Name		From - To (MM/YY – MM/YY)	
Davar's college of Commerce		1993 - 1994	
Address	**City**	**State**	**Zip**
Mulla House, Rear Entrance (Opp. Bombay House), 3rd COUNTER, 3rd Floor, Homi Mody Cross Street No.1, Flora Fountain	Mumbai, Maharashtra 400001, India		
Diploma/Degree obtained, if any			
Diploma in Personal Secretaryship			

School Name		From - To (MM/YY – MM/YY)	
University of Mumbai		1990 -1993	
Address	**City**	**State**	**Zip**
Mahatma Gandhi Road, Mantralaya, Fort, Mumbai	Maharashtra 400032, India		
Diploma/Degree obtained, if any			
Bachelor in Art History			

School Name		From - To (MM/YY – MM/YY)	
HOLY CROSS CONVENT HIGH SCHOOL		06/78-05/88	
Address	**City**	**State**	**Zip**
K'VILLA, UTHALSAR ,	THANE	India	400601
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2025 - Present	[redacted]	Plainsboro	NJ	[redacted]
04/2013 - 11/2025		India 400610		
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Validus Pharmaceuticals LLC			08/2026 - Current	
Business Address		**City**	**State**	**Zip**
40 Cotters Lane, Suite A		East Brunswick	NJ	08816
Phone	**Title**		**Number of Employed Hours**	
(973) 265-2777	Designated Representative		~ 173 hours	
Description of Duties				
state licensing to maintain facility licensure documentation and operational readiness in strict adherence to state guidelines and Federal DSCA for all Advagen Holding entities				

Business Name			From - To (MM/YY – MM/YY)	
Advagen Pharma			12/2025 - Current	
Business Address		**City**	**State**	**Zip**
50 Millstone Road, Building 200, 1st Floor, Suite 180		East Windsor	NJ	08520
Phone	**Title**		**Number of Employed Hours**	
(609) 269-8128	Executive Assistant		~ 1,566 hours	
Description of Duties				
state licensing to maintain facility licensure documentation and operational readiness in strict adherence to state guidelines and Federal DSCA for all Advagen Holding entities and other Adminstrative Managerial responsibilities				

Business Name			From - To (MM/YY – MM/YY)	
Rubicon Research Ltd			08/2019 - 11/2025	
Business Address		**City**	**State**	**Zip**
MedOne House, Plot No. B-75, Road No. 33, Wagle Estate, Thane West		400604, Maharashtra, India		
Phone	**Title**		**Number of Employed Hours**	
+91 22 61414000	Executive Assistant		~ 13,217 hours	
Description of Duties				
Providing high level of administrative & secretarial support to the Director/s, Monitoring Supply chain, suspicious orders. Day to day stock supervision,SOP development& its implementation for its distribution &storage among others				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

N/A

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A - No discipline to disclose

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Preethy Louise Rego, **certify that as the designated representative for**

Validus Pharmaceuticals LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. PR I am at least 21 years of age;
3. PR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. PR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. PR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. PR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. PR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Preethy Louise Rego

Print Name (First, Last)

Rego

Original Signature (electronic, copies or stamps not accepted)

08/26/2026.

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Preethy Louise Rego

Print Name (First, Last)

Rego

Original Signature (electronic, copies or stamps not accepted)

08/26/2026

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Mercer

I, Preethy Rego, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Rego

Original Signature Preethy Louise Rego

08/26/2026

Date

Subscribed and Sworn to before me this 26th day of August.

Notary Public Signature

ADELFA VICTORIANO NOTARY PUBLIC ID # 50074321 COMMISSION EXPIRES 01/08/25 STATE OF NEW JERSEY

(Seal)

Employee List

As on 7/30/2026 _ Validus Employee list

Employee Name	Designation
1. Jeffrey S Werner	National Account Manager
2. Emile Williams	COO
3. Kenneth Abreu	Director Market access
5. Tanille Edwards	Sales Rep
6. Daniel Rowell	Director Sales
7. John Eltabei	Sales Rep
9. Shawn Meyer	Sales Rep
10. Priscilla Castellanos	Sales Rep
12. Jennifer Delano	Sales Rep
13. Anna Belovsky	Sales Rep
14. Sakshi Shinde	Key Account Coordinator
15. Emeka Ogbonna	Key Account Manager

4FF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10) ■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10)

Section 1: General Information

Facility Name: bioFire Diagnostics, LLC

Physical Address: 1590 S 5200 W

City: Salt Lake City State: UT Zip: 84104

Mailing Address (if different from physical address): Attn: Sandra Perreand c/o Mary Vomund, 595 Anglum Road

City: Hazelwood State: MO Zip: 63042

Telephone: 801-736-6354 Website: www.biomerieux.com

Name of Designated Representative (DR): Scott Raymond Roney

Licensing Company Email: statelicensing@biomerieux.com DR Email: statelicensing@biomerieux.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies ☐ Practitioners ■ Hospitals ■ Wholesalers ☐ Veterinarians ■ Others: other healthcare delivery sites that provide diagnostic testing	☐ Dangerous Drugs ☐ Controlled Substances ■ *Medical Products (medical devices, equipment, supplies, gases) in vitro diagnostic tests, reagents and equipment ☐ Others:	☐ Manufacturer ☐ Repacker ☐ Reverse Distributor ■ Warehouse ☐ Retail pharmacy wholesale distributor ☐ Others:

Section 2: ONLY COMPLETE THIS SECTION IF THE COMPANY IS WHOLESALING [a]Medical Products (medical devices, equipment, supplies and gases). Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 3 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

05 August 26
Date

Section 4: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Louisville IDC UPS Healthcare
Address: 2260 Outer Loop City: Louisville State: KY Zip: 40219
Name: Mira Loma IDC UPS Healthcare
Address: 11991 Landon Dr City: Mira Loma State: CA Zip: 91752
Name: Pedricktown IDC UPS Healthcare
Address: 7 Gateway Blvd City: Pedricktown State: NJ Zip: 08067
Name:
Address: City: State: Zip:

Section 5: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): bioFire Holdings, Inc.
Corporation/Organization Name: bioFire Diagnostics, LLC
Mailing Address: 1590 S 5200 W
City: Salt Lake City State: UT Zip: 84104
Telephone: 636-399-4478 Email: statelicensing@biomerieux.com
Contact Person Name: Sandra Perreand

Section 7: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 8: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 9: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 10: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale [a]Medical Products (medical devices, equipment, supplies, gases). (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Products (medical devices, equipment, supplies, gases), supply a copy of proof of insurance (NAC 639.6957).** The Medical Products wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 9)				
• **Submit Fingerprints** following instructions found at: https://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20NRS%20639.500%20-%20Effective%2001.07.2026%20-%20Wholesaler%20-%20Post%20on%201.26.26.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

bioFire Diagnostics, LLC

Facility Name

Sarah Mauney

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

05August2026

Date

Board Use Only	Date Received: 8/10/26	Amount: $1000 CK 0000830345

BIOMÉRIEUX	bioMérieux Salt Lake City Campus Locations

For the BioFire Product Line (BPL) and bioMérieux Salt Lake City QMS, the table below details business boundaries and registered activities for each location.

Campus*	Building Address	Registered Activities
Salt Lake City Sites Facility ID Number: F000086	515 Colorow Drive Salt Lake City, UT 84108	Design and Manufacture of PCR Systems for the Detection of Pathogens, Administration
	1001 South 4800 West Salt Lake City, UT 84104	Reagent Production
	1201 South 4800 West Salt Lake City, UT 84104	Administration, Final Product QC, Template Control Manufacturing
	1590 S 5200 West Salt Lake City, UT 84104	Distribution Warehouse
	415 Bearcat Drive Salt Lake City, UT 84115	Service

*bsi definition of ***Campus*** under MDSAP are as follows (06.03.2020):

Campus: Either

- A group of facilities within a maximum range of one kilometer, or
- A group of geographically close facilities (within 60-minute drive), if not more than one of these facilities would require a facility-specific Regulatory Authority-issued certificate (such as the issuance of a GMP Certificate (ANVISA) or a Registration Certificate (PMDA)). In either case, the facilities in the group shall be operated by the medical device organization under a single QMS. The management for, and the activities within, the group of facilities must correlate to the realization of the finished medical devices included in the scope of certification.

Additional Notes:

- A group of buildings sharing the same street address (same street and number) is seen as a single facility and not as a campus.
- A campus may include multiple facilities with Regulatory Authority-issued facility identifier (e.g. FEI issued by the FDA).

Attachment to bioFire Diagnostics, LLC's Out-of-State Wholesaler Application (Nevada Board of Pharmacy)

bioFire Diagnostics, LLC's Ownership

bioFire Holdings, Inc. (Parent, 100%)
100 Rodolphe St,
Durham, NC 27712



bioFire Diagnostics, LLC
1590 S 5200 W
Salt Lake City UT 84104

Attachment to bioFire Diagnostics, LLC's Out-of-State Wholesaler Application (Nevada Board of Pharmacy)

Description of Operations:
bioFire Diagnostics, LLC is a wholly-owned subsidiary of bioMérieux, Inc. bioFire Diagnostics, LLC, ("bioFire") is an own-label distributor of in vitro diagnostic tests which include both reagents and equipment. bioFire's product is sold to wholesalers and directly to hospitals, and other healthcare delivery sites that provide diagnostic testing.

bioFire's office hours of operation are Monday through Friday from 8:00 a.m. to 5:00 p.m.

BioFire Diagnostics, LLC Officers

Name	Title	Residence Address	Ownership %
Bart Van Den Brand	Sr. V.P. Site Operations Americas	[redacted]	0%
Sarah Mauney	V.P. General Counsel, Global Litigation N. America		0%

Parent Company:
BioFire Holdings, Inc. (100%)
100 Rodolphe St,
Durham, NC 27712

Product Code	Description	Premarket Submission Number (510k):
NSU	BioFire FilmArray Torch instrument	K160068
PCH	BioFire FilmArray Gastrointestinal (GI) Panel	K242367
PCH	BioFire FilmArray Gastrointestinal (GI) Panel Mid	K243885
PLO	BioFire FilmArray Meningitis/Encephalitis (ME) Panel	K160462
QDP	BioFire FilmArray Pneumonia Panel	K243222
PEN, PEO, PAM	BioFire Blood Culture Identification 2 (BCID2) Panel	K243759
QOF	BioFire Respiratory Panel 2.1	DEN200031
QJR	BioFire Respiratory Panel 2.1-EZ	EUA (no longer on market)
QSN	BioFire Joint Infection (JI) Panel	DEN200066
QMV	BioFire FilmArray Tropical Fever Panel	K243463
NSU	BIOFIRE SPOTFIRE Module	K213954
QOF, OCC, OEM, OOU, OTG, OZE, OZX, OZY, OZZ	BIOFIRE SPOTFIRE Respiratory (R) Panel	K213954
QOF, OCC, OTG, OZE	BIOFIRE SPOTFIRE Respiratory (R) Panel Mini	K230719
QOF, OEM, OOU, OTG, OZE, OZX, OZY, OZZ, OCC, NSU, PGX	BIOFIRE SPOTFIRE Respiratory/Sore Throat Panel	K232954
QOF, NSU, OCC, OZE, PGX	BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel Mini	K243544

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "BIOFIRE DIAGNOSTICS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF MARCH, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "BIOFIRE DIAGNOSTICS, LLC" WAS FORMED ON THE TENTH DAY OF JANUARY, A.D. 2014.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5463662 8300

SR# 20260512272

Authentication: 203317421

Date: 03-11-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LICENSE

BioFire Diagnostics LLC

EFFECTIVE **03/25/2026**

EXPIRATION **09/30/2027**

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

14269399-1710 Pharmacy - Class C

Distributor

DBA:

IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

BIOFIRE DIAGNOSTICS LLC
1590 S 5200 W
SALT LAKE CITY UT 84104

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE

DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING

ACTIVE LICENSE

EFFECTIVE DATE: **03/25/2026**

EXPIRATION DATE: **09/30/2027**

ISSUED TO: **BioFire Diagnostics LLC**
1590 S 5200 W
Salt Lake City UT 84104

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

14269399-1710 **Pharmacy - Class C** **Distributor**

DBA:

Form #1

Details for BioFire Diagnostics LLC

License Information

	BioFire Diagnostics LLC
	Salt Lake City UT 84104 United States
	Pharmacy
	Pharmacy - Class C
	14269399-1710
	Application
	Active
	03/25/2026
	09/30/2027
	NO DISCIPLINARY ACTIONS WITHIN THE TIME FRAME ESTABLISHED IN UTAH CODE 63G-4-106 AND 107**
	N/A

Distributor

Reports require Adobe® Acrobat® Reader™.

This information is accurate as far as is contained in the Division's official records. It does not reflect whether an entity required to maintain a current registration with the Division of Corporations is current in that registration. You can verify such status at https://secure.utah.gov/bes/bes (opens in new window). Additionally, this verification does not show a complete license history or interruptions of licensure. Original issue dates listed

ACORD®

EVIDENCE OF PROPERTY INSURANCE

DATE (MM/DD/YYYY) 02/04/2026

THIS EVIDENCE OF PROPERTY INSURANCE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE ADDITIONAL INTEREST NAMED BELOW. THIS EVIDENCE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS EVIDENCE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE ADDITIONAL INTEREST.

AGENCY PHONE (A/C, No, Ext): 1-877-945-7378 Willis Towers Watson Midwest, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	**COMPANY** Factory Mutual Insurance Company 270 Central Ave Johnston, RI 029194949
FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@wtwco.com	
CODE: SUB CODE:	
AGENCY CUSTOMER ID #:	
INSURED BioFire Diagnostics LLC 515 Colorow Drive Salt Lake City, UT 84108	LOAN NUMBER POLICY NUMBER 1161526 EFFECTIVE DATE 01/01/2026 EXPIRATION DATE 01/01/2027 ☐ CONTINUED UNTIL TERMINATED IF CHECKED *THIS REPLACES PRIOR EVIDENCE DATED:*

PROPERTY INFORMATION

LOCATION/DESCRIPTION
US030: West Warehouse 1590 S 5200 W, Salt Lake City, UT 84104

THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS EVIDENCE OF PROPERTY INSURANCE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS *SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.*

COVERAGE INFORMATION

PERILS INSURED ☐ BASIC ☐ BROAD ☐ SPECIAL ☒ All Risk

COVERAGE / PERILS / FORMS	AMOUNT OF INSURANCE	DEDUCTIBLE
Policy Limit of Liability	$987,241,013	
Automatic Coverage - New Location - 90 Days - Per Location	$34,843,800	
Misc Property - Per Location	$23,229,200	
Misc Property - Off-Premises	$2,903,650	
All Other Losses Deductible		$290,365

REMARKS (Including Special Conditions)

This certificate does not amend, extend, or alter the coverage afforded by the policy.

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

ADDITIONAL INTEREST

NAME AND ADDRESS Freeport West 1505 S. Redwood Road Salt Lake City, UT 84104	☐ ADDITIONAL INSURED ☐ LENDER'S LOSS PAYABLE ☐ LOSS PAYEE ☐ MORTGAGEE LOAN # AUTHORIZED REPRESENTATIVE

ACORD 27 (2016/03)

© 1993-2015 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

SR ID: 29345851 BATCH: 4311097 CERT: W43921070

GENERAL SURETY RIDER

To be attached and form a part of

Bond No.	800227420
For	NV Pharmaceutical Wholesaler Bond - 100000 UP 1-23 (License & Permit) : License & Permit (900)
Dated effective	04/15/2026 (MONTH, DAY, YEAR)
Executed by	BioFire Diagnostics, as Principal, (PRINCIPAL)
And by	Atlantic Specialty Insurance Company, as Surety, (SURETY)
And in favor of	Nevada State Board of Pharmacy (OBLIGEE)

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

INFORMATION	
Adding Addresses for Service	515 Colorow DR Salt Lake City, UT 84108-1248 And 1590 S 5200 West Salt Lake City,UT 84104

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective **04/15/2026**
(MONTH, DAY, YEAR)

Signed and Sealed **04/15/2026**
(MONTH, DAY, YEAR)

BioFire Diagnostics
PRINCIPAL

BY _____
TITLE

Atlantic Specialty Insurance Company
SURETY

BY _____
Doritza Mojica, ATTORNEY-IN-FACT

intact INSURANCE

Surety Bond No: 800227420

BioFire Diagnostics
Nevada State Board of Pharmacy

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Doritza Mojica**, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON D. NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2030

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 15th day of April 2026

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2030

_____
Kara I..B. Barrow, Secretary

Please direct bond verifications to [illegible]

Telephone: +1 860 278 1320
Website: wtwco.com

April 17, 2026

BIOMERIEUX INC
Attn: Sarah Mauney
100 Rodolphe Street
Durham, NC 27712

RE: **April – New Bonds (8)**
April – Riders (8)
Commission: 32.5%

We are pleased to enclose the above referenced bond you requested. This bond was executed based upon the information you provided. We urge you to check all of the information enclosed, including the Power of Attorney, signatures, dates, amounts, description, bond form and any other attachments.

Please be sure to affix the bond with the proper signature and seal.

If a premium is charged, our invoice will follow under separate cover and premium payment for this bond is due upon receipt. **Please note that the first term's premium related to any renewable obligation is considered fully earned.**

Willis Towers Watson negotiates commission rates with certain insurers on a corporate level. If the rate on your placement is lower than the negotiated rate, Willis Towers Watson may collect the difference directly from the insurer. These payments will not increase the cost of your bonds or otherwise impact your premium or rates. Details of these arrangements where there is compensation beyond the base compensation detailed in your commission schedule can be found at: https://www.wtwco.com/en-us/notices/p-c-national-commission-rates.

Thank you for the opportunity to service your surety needs. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Rhi Portillo
Rhi.Portillo@wtwco.com

Willis Towers Watson Northeast, Inc.
10 State House Square, 11th Floor
Hartford, CT 06103

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 800227420

Application/License No. _____

BioFire Diagnostics (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1001 South 4800 West, Salt Lake City, UT 84104 (Address of Applicant/Principal), as PRINCIPAL, and Atlantic Specialty Insurance Company (Surety Company), a corporation organized under the laws of the state of NY (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 605 Highway 169 North, Suite 800 , Plymouth, MN 55441 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 15, 2026 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 15th day of April, 2026.

APPLICANT/PRINCIPAL

BioFire Diagnostics
COMPANY

By: _____
Authorized Representative

SURETY

Atlantic Specialty Insurance Company

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By: _____
Surety Company's Representative

Doritza Mojica, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

_____
Witness Haley Pulley

_____
Witness Makayla Alexis

Countersigned by:

_____
Nevada Resident Agent Malerie Janet Williams
Non-Resident License No.: 4156693

Posted February 20, 2020

intact INSURANCE

Surety Bond No: 800227420

Power of Attorney

BioFire Diagnostics
Nevada State Board of Pharmacy

KNOW ALL MEN BY THESE PRESENTS, that ATLANTIC SPECIALTY INSURANCE COMPANY, a New York corporation with its principal office in Plymouth, Minnesota, does hereby constitute and appoint: **Doritza Mojica**, each individually if there be more than one named, its true and lawful Attorney-in-Fact, to make, execute, seal and deliver, for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof; provided that no bond or undertaking executed under this authority shall exceed in amount the sum of: **unlimited** and the execution of such bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof in pursuance of these presents, shall be as binding upon said Company as if they had been fully signed by an authorized officer of the Company and sealed with the Company seal. This Power of Attorney is made and executed by authority of the following resolutions adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the President, any Senior Vice President or Vice-President (each an "Authorized Officer") may execute for and in behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and affix the seal of the Company thereto; and that the Authorized Officer may appoint and authorize an Attorney-in-Fact to execute on behalf of the Company any and all such instruments and to affix the Company seal thereto; and that the Authorized Officer may at any time remove any such Attorney-in-Fact and revoke all power and authority given to any such Attorney-in-Fact.

Resolved: That the Attorney-in-Fact may be given full power and authority to execute for and in the name and on behalf of the Company any and all bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof, and any such instrument executed by any such Attorney-in-Fact shall be as binding upon the Company as if signed and sealed by an Authorized Officer and, further, the Attorney-in-Fact is hereby authorized to verify any affidavit required to be attached to bonds, recognizances, contracts of indemnity, and all other writings obligatory in the nature thereof.

This power of attorney is signed and sealed by facsimile under the authority of the following Resolution adopted by the Board of Directors of ATLANTIC SPECIALTY INSURANCE COMPANY on the twenty-fifth day of September, 2012:

Resolved: That the signature of an Authorized Officer, the signature of the Secretary or the Assistant Secretary, and the Company seal may be affixed by facsimile to any power of attorney or to any certificate relating thereto appointing an Attorney-in-Fact for purposes only of executing and sealing any bond, undertaking, recognizance or other written obligation in the nature thereof, and any such signature and seal where so used, being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

IN WITNESS WHEREOF, ATLANTIC SPECIALTY INSURANCE COMPANY has caused these presents to be signed by an Authorized Officer and the seal of the Company to be affixed this first day of January, 2023.

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

By _____
Sarah A. Kolar, Vice President and General Counsel

STATE OF MINNESOTA
HENNEPIN COUNTY

On this first day of January, 2023, before me personally came Sarah A. Kolar, Vice President and General Counsel of ATLANTIC SPECIALTY INSURANCE COMPANY, to me personally known to be the individual and officer described in and who executed the preceding instrument, and she acknowledged the execution of the same, and being by me duly sworn, that she is the said officer of the Company aforesaid, and that the seal affixed to the preceding instrument is the seal of said Company and that the said seal and the signature as such officer was duly affixed and subscribed to the said instrument by the authority and at the direction of the Company.

ALISON D. NASH-TROUT
NOTARY PUBLIC - MINNESOTA
My Commission Expires
January 31, 2030

_____
Notary Public

I, the undersigned, Secretary of ATLANTIC SPECIALTY INSURANCE COMPANY, a New York Corporation, do hereby certify that the foregoing power of attorney is in full force and has not been revoked, and the resolutions set forth above are now in force.

Signed and sealed. Dated 15th day of April, 2026

ATLANTIC SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1986 NEW YORK

This Power of Attorney expires
January 31, 2030

_____
Kara L.B. Barrow, Secretary

Please direct bond verifications to [illegible]

Telephone: +1 860 278 1320
Website: wtwco.com

April 17, 2026

BIOMERIEUX INC
Attn: Sarah Mauney
100 Rodolphe Street
Durham, NC 27712

RE: **April – New Bonds (8)**
April – Riders (8)
Commission: 32.5%

We are pleased to enclose the above referenced bond you requested. This bond was executed based upon the information you provided. We urge you to check all of the information enclosed, including the Power of Attorney, signatures, dates, amounts, description, bond form and any other attachments.

Please be sure to affix the bond with the proper signature and seal.

If a premium is charged, our invoice will follow under separate cover and premium payment for this bond is due upon receipt. **Please note that the first term's premium related to any renewable obligation is considered fully earned.**

Willis Towers Watson negotiates commission rates with certain insurers on a corporate level. If the rate on your placement is lower than the negotiated rate, Willis Towers Watson may collect the difference directly from the insurer. These payments will not increase the cost of your bonds or otherwise impact your premium or rates. Details of these arrangements where there is compensation beyond the base compensation detailed in your commission schedule can be found at: https://www.wtwco.com/en-us/notices/p-c-national-commission-rates.

Thank you for the opportunity to service your surety needs. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Rhi Portillo
Rhi.Portillo@wtwco.com

Willis Towers Watson Northeast, Inc.
10 State House Square, 11th Floor
Hartford, CT 06103

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG bioFire Diagnostics, LLC MDEG License # (if applicable) N/A

Physical Address 1590 S 5200 W

City Salt Lake City State UT Zip 84104

Mailing Address (if different from physical address) (Attn; Sandra Perreand c/o Mary Vomund, 595 Anglum Road

City Hazelwood State MO Zip 63042

Telephone 919-620-2000 Website www.biomerieux.com

Licensing Company Email statelicensing@biomerieux.com

Section 2: Personal Information

First Scott Middle Raymond Last Roney

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 1590 S 5200 W

City Salt Lake City State UT Zip 84104

Telephone 919-620-2000 Email statelicensing@biomerieux.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Salt Lake Community College		2000 - 2003	
Address	**City**	**State**	**Zip**
4600 South Redwood RD	Salt Lake City	UT	84123
Diploma/Degree obtained, if any			
None			

School Name		From - To (MM/YY – MM/YY)	
Highland High School		1982 - 1985	
Address	**City**	**State**	**Zip**
2166 S 1700 East	Salt Lake City	UT	84106
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
6/1998 - Present	[redacted]	Salt Lake City	UT	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
BioFire Diagnostics, LLC (fka bioMerieux, Inc.)			2/2017 - Present	
Business Address		**City**	**State**	**Zip**
1590 S 5200 W		Salt Lake City	UT	84104
Phone	**Title**		**Number of Employed Hours**	
801-736-6354	Material Handling Manager 1		40+ hours / week	
Description of Duties				
Material Manager, shipping supervisor, involved with finished goods Inventory, interact with logistics support				

Business Name			From - To (MM/YY – MM/YY)	
Please see the attached Resume for additional employment information.				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) _____ Date _____

I, Scott Raymond Roney, **certify that as the MDEG Administrator for**

bioFire Diagnostics, LLC,

that I (initial that you have read and meet the following requirements):

1. SR Have a high school diploma or its equivalent;
2. SR Have
   - ✓ a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   - b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SR Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SR Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Scott Raymond Roney
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7-6-2026
Date

Board Use Only	Date Received: 8/10/26

SCOTT PONEY
[redacted]

Summary

An Operations Manager with expertise in leading multiple organizations including marketing, operations, inside sales, warehousing, transportation and client support functions. Track record of success in lowering operational costs by focusing on quality and productivity. Strong focus on the customer experience both from a support and product quality perspective.

Core Competencies

Tactical Operational Leadership
Purchasing Negotiation
Marketing Logistics
Packaging and Distribution
Strategic Planning
Contract Negotiation
Building Maintenance
SAP and Oracle
ISO 9001 Leadership
Retail Sales
Transportation Carrier Negotiation
Budget and Finance
Coaching and Development
Team Building
Empowering the Employee
Leadership
IT Planning and Phone System
Salesforce
Business Software Implementation
OHSA – Safety and Health Certified

Professional Experience

bioMerieux – Salt Lake City, UT
With over $2.0 billion in revenue and over 10000+ employees, bioMerieux sells and supports the Healthcare Industry globally.

Material Manager – West Warehouse ***June 2020 – Present***
Currently responsible for the Shipping and Prepack Teams. Past role included managing the Swing and Night Shifts at multiple warehouses. Oversee multiple groups including but not limited to Receiving/Quantifying, Kanban, Prepack and the Logistic Teams. Overseeing 20+ Team Members along with Supervisor and Lead rolls. Daily interactions with multiple groups including HR, Inventory Control, Quality Control, Logistics and other Leadership Teams.

- Promoted from Shipping Supervisor to Materials Manager after 2 years
- Helped oversee two warehouse moves to new locations
- Responsible for overall headcount with Fulltime or temporary Team Members.
- Have taken several Management Classes that BioFire offers
- Bert Member since 2017 (Biofire Emergency Response Team)
- Took lead roll in the Prepack area for both Days and Swings
- Setup an Inventory Scanning Program using existing Team Members that helps keep our Inventory Accuracy Rate at 99%.

BioFire Diagnostics – Salt Lake City, UT
$500M in revenue, with 2000+ employees that sell and support to the Healthcare Industry globally. BioFire Diagnostics a subsidiary of BioMerieux with revenues exceeding $2B with 10,000 team members worldwide.

Shipping Supervisor ***Feb 2017 – June 2020***
Responsible for Domestic Shipping, Prepack and Finished Goods Inventory with 8 employees. Daily interactions and Logistical Support for several different departments. Work on a daily basis with outside vendors including Packaging and Transportation.

- Promoted from Shipping Lead to Shipping Supervisor after 1 year
- Part of the SAP Implantation Team for the Domestic Shipping and was award for Outstanding Performance
- Inventory accuracy rate for the Reagents and Instruments at the West Warehouse is 99%,
- Increase shipping output from 100 orders a day to 300 orders a day with Team Building
- Responsible for $30m plus of inventory on a daily basis
- Have taken several Management Classes that BioFire offers
- Bert Member since 2017 (Biofire Emergency Response Team)

Goodman Distribution – Salt Lake City, UT
$10M in revenue, with 5 employees that sell and service the Heating and Air Conditioning industry for the Utah territory. Goodman Distribution is a subsidiary of Daikin Inc. with revenues of $20B and employees over 60,000 employees worldwide.

Warehouse Manager ***Mar 2016 – Jan 2017***
Responsible for Receiving, Shipping, Inventory and Order Fulfillment Group with 4 employees and local transportation services. Interaction with Vendors, Direct Customers and Sr. Managers at different facility's around the US.

- 2015 Branch of the Year Award
- Inventory accuracy at 98%,
- Order Fulfillment accuracy at 99%
- Responsible for $2m plus of inventory
- Customer Service Bonus received each qtr.

Weir Minerals North America – *Salt Lake City, UT*
$35M in revenue, with 150 unionized employees that develop and market commercial rubber and screens for the energy marketplace. Weir Minerals North America is part of a group within Weir Group LLC, with $50B in revenue along with 50,000 employees manufacturing and supporting the Energy Field.

Distribution and Warehouse Manager ***Sept 2012 – Feb 2015***
Oversaw the Shipping, Receiving and Warehouse Group with 8 Employees on multiple shifts.
Managed Union Contract for Shipping, Receiving and Warehouse employees
Responsible for multiple warehouses and transportation in SLC area
Interaction with Engineering and Customer Service on a daily basis

- Increased on-time delivery from 90% to 95% by managing employees time and production in the group
- Increased Customer Service Levels in the group by communication and training with all internal departments
- Worked with the Inventory Team on daily cycle counts and a yearly physical inventory

- Team Member of the Safety Committee which drove improvement year over year

ONYX GRAPHICS, INC – ***Midvale, UT***
$10M in revenue, 50-employee global company that develops and markets commercial printing software and solutions for the wide format digital color printing marketplace. Part of the Display Graphics Systems Business Unit of Océ, now a group within Canon, Inc., a $42.2B (¥3.6T) 197,000 employee manufacturer of imaging and optical products.

Technical Support and Operations Manager ***Feb 2009 – July 2012***
Oversaw the Technical Support Group with 8 Employees on multiple shifts.
Customer Experience using Stats and Phone Monitoring
Responsible for Phone System and CRM Database
Interaction with Engineering on Customer Escalations and Bug Fixes

- Increased Software Upgrades by helping develop a Service Agreement Plan for Customers from $1.8 million to $2.3 million per year
- Increased Customer Satisfaction level to 90% from 60% by empowering the employee to see things through to the end
- Increased the First Call Resolution from 60% to 85% and Email from 35% to 60%
- Increased Engineering output by 30% using data and customer communication. Bring the right groups together to make the decision's and holding them accountable each week
- Implemented a Global Technical Support staff to handle Asia, EMEA, Latin America and US customers
- Implemented a Pay for Support plan which covered our Technical Support Group Expenses to just over 50% of budget

Operations Manager ***Feb 2006 – Feb 2009***
Oversaw all aspects of the Operation which included Production, Customer Service, Call Center, Shipping and Receiving and Building Facilities. Managed 6 Employees on multiple shifts. Inbound Call Center generated for the company $40K in Sales each month. Oversaw all Tradeshows and Company Events. This would also included Open Houses, Dealer Roundtables and Special Guest. Would included Travel and setup for the events.

- Setup an Outbound Call Center to generate Revenue from Leads and Tradeshows
- Holding inventory levels of less than $100K per month with 4 different products being shipped daily
- Implemented SAP and Salesforce into the Order Entry Group which allowed us to generate $35k per day in orders and shipped to the customer the same day
- Maintained a 99% order accuracy rate by implanting audits, customer surveys, reports and along with a QA process in Shipping
- Reduced Shipping and Transportation cost from $90k to $9k by changing from a Expense to a Revenue generator and still keeping the Customer Experience a positive one

Shipping and Receiving Manager ***Feb 2005 – Feb 2006***
Oversaw all aspects of Shipping of Software and the distribution to customers.

- Reduced inventory by $25k while increasing warehouse space for finished product
- Implemented cost reductions by adding Shipping System, workflow and QA process

KARMAN KITCHENS – ***Murray, UT***
Cabinetry by Karman has been in business for over 50 years. Karman is leader in manufacturing fine kitchen and bath furniture. With Sales of $15 million per year and over 100 employees Karman has been able to maintain a Positive Customer Experience

Transportation and Distribution Manager ***Jun 2002 – Dec 2004***
Oversaw all aspects of Shipping of kitchen cabinets and the distribution to customers. Managed 2 shifts with 5 dock workers and 2 office staff members.

- Implemented a Trucking Program that saved the company over $100k per year
- Increased on time deliveries by 75% using a single trucking carrier

EVANS AND SUTHERLAND – ***Salt Lake City, UT***
Evans & Sutherland is the world's first computer graphics company and has developed and advanced computer graphics technology for almost for decades. Focusing primarily on digital planetariums and digital cinemas worldwide. With sales of over $50 million per year has been able to maintain a Positive Customer Experience

Inventory Control and Store Room Manager ***Apr 1999 – Apr 2002***
Cycle Counting Audit's, Offsite Parts Warehouse. Weekly Management Meetings and projects. Managed 10 fulltime store employee's and 1 Warehouse Employee

- Implemented a Parts Carousal to handled over ten thousand parts
- Increased cycle counting accuracy by 30% using audits and detail reporting

Transportation and Distribution Manager ***Jun 1993 – Apr 1999***
Overseen all Global shipments. Managed and Outsourced to a 3rd Party Logistics Company. Managed 5 Fulltime Employees and 1 3rd party Logistic Employee. Managed offsite Warehousing and Delivery Fleet

- Outsourced Transportation and Warehousing to a 3rd party which saved the company over $500k per year
- Increased on time deliveries and customer satisfaction by 50% by consolidating 10 shipping carriers to 3 carriers
- Served as a critical part of the Oracle Implementation team and ISO 9001 Teams

Shipping and Receiving Specialist ***Aug 1987 – Jun 1993***
Domestic and International Shipping. Deliveries and pickups from local vendors

- Maintained a fleet of vehicles for the company. Regular maintain and reporting of mileage to supervisor on a monthly base

Education

Salt Lake Community College, Salt Lake City, UT
Highland High School, Salt Lake City, UT

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: bioFire Diagnostics, LLC
Pharmacy/Wholesaler License # (if applicable):
Physical Address: 1590 S 5200 W
City: Salt Lake City State: UT Zip: 84104
Mailing Address (if different from physical address): (Same)
City: State: Zip:
Telephone: 801-736-6354 Website: www.biomerieux.com
Licensing Company Email: statelicensing@biomerieux.com

Section 2: Personal Information

First: Scott Middle: Raymond Last: Roney
Alias(es, nicknames, name changes, etc.): N/A
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X
Mailing Address: 1590 S 5200 W
City: Salt Lake City State: UT Zip: 84104
Telephone: 801-736-6354 Email: statelicensing@biomerieux.com
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Salt Lake Community College		1-2000-6-2002	
Address: 4600 S Redwood Rd	City: Salt Lake City	State: UT	Zip: 84123
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Highland High School		8-1982/6-1985	
Address: 2166 S 1700 E	City: Salt Lake City	State: UT	Zip: 84106
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1998 - Present	[redacted]	Salt Lake City	UT	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
BioFire Diagnostics, BioMerieux			02/2017 - Present	
Business Address		City	State	Zip
1590 S 5200 W		Salt Lake City	UT	84104
Phone	Title		Number of Employed Hours	
801-736-6354	Material Manager		18,720	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
N/A				
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
N/A				
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6-24-2026
Date

I, Scott Roney, certify that as the designated representative for

bioFire Diagnostics, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SR I am at least 21 years of age;
3. SR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Scott Roney
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6-24-2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Scott Roney

Print Name (~~First, Last~~)

Original Signature (electronic, copies or stamps not accepted)

6-24-2026

Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Salt Lake

I, Scott Roney, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6-24-2026

Date

Subscribed and Sworn to before me this 24 day of June 2026

Notary Public Signature

KELLY OAKS
Notary Public - State of Utah
Comm. No. 734347
My Commission Expires on
Nov 27, 2027

(Seal)

Name
Aaron MENGWASSER
Adam SMITH
Aliya LUND
Anthony FERNELIUS
Anthony HERNANDEZ
Anthony MAZZA
Arlett LOPEZ-VALDOVINOS
Ashantai YUNGAI
Ashley BOESE
Ayden BERNARD
Bao NGUYEN
Benito JUAREZ
Benjamin MILLER
Billy SAM
Binh NGUYEN
Brianna FEASTER
Bryan GARCIA
Carmelo VELEZ III
Charana DELACRUZ
Charles WILLIAMS
Chi NGUYEN
Collin FEASTER
Conor FELTON
Cordero DIXON
Dallan ANDERSON
Daniel VELASQUEZ
David ONG
David PILCHER
David SHOBER
Derek CROCKETT
Desirae TRUJILLO
Dillon BREWER
Dustin HINOJOSA-GARCIA
Elias PADUA
Eric RENOVA-ORNELAS
Estefany VALDEZ ALARCON
Fabian MANRIQUEZ
Fatima SAIDYKHAN
Franklin BELL
Garrison SAVINI
Heath RIDDLE
Isaiah MIRANDA
Isiah YANG
Jack PARNELL

James NICOLAS
Jason LOPEZ
Jason WINEGAR
Jefete AFONSO
Jennifer SOTO
Jeramy WARNER
Jeran BURGESS
Jeremy HALE
Joli HABOKO
Joseph MUSSER
Joshua HILLYARD
Joshua INMAN
Juan NINO
Kaipo MAUSIA
Kathryn VORASANE
Kayla NELSON
Kenya MARTINEZ
Kevin GARVOILLE
Kevin SULLIVAN
Kirk EWELL
Kody REES
Kyle BOLES
Kyle DAYTON
Kyle DURR
Lindsey ROCK
Maribel YANDAR
Marisol SANCHEZ
Mark DE LEON
Mary SPACKMAN
Matthew BENDHEIM
Max EVANS
Megan CARTER
Melanie GALVAN
Michael COURTNEY
Michael NICEWANDER
Michelle GREEN
Mohammed MAHDI
Nathaly VALLADARES
Nathan STRAND
Nestor CARRION
Nick ROBERTS
Nolan MATTSON
Patsy VERA
Philip LOKIRU
Preston MCCUBBIN

Quinnton GOODWIN
Rasela LIMUTAU
Robert CHAIREZ
Robert MAY
Ryan TUMANUVAO
Samuel BRIGGS
Scott RONEY
Shawny GOUGH
Sherrie GOFF
Sherry SANDERS
Shunta HARPER
Skylar RICKETTS
Steven PALMER
Tanya LEVI
Taylor JOHNSON
Timothy TEAH
Tina TIDWELL
Todd NATE
Tram VO
Von UYEHARA
Wendy WARENSKI
William BAUMAN
William PERKINS
Yeshoua NEGRETE
Zachariah KNOWLTON
Zachary SWANSON

4GG

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: GC Biopharma USA, Inc.

Physical Address: 500 Frank W. Burr Blvd., Suite 230, Mailbox #48

City: Teaneck State: NJ Zip: 07666

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: (201) 592-0561 Website: www.gcbiopharma.us

Name of Designated Representative (DR): Brian Kelly

Licensing Company Email: state@gcbiopharmausa.com DR Email: state@gcbiopharmausa.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☑ Pharmacies	☑ Dangerous Drugs	☑ Manufacturer (Virtual)(This company will only sell prescription drug product from its parent company (a single manufacturer). As such, fingerprints and a $100,000 bond is not required Reference NAC 639.593(8)(e)
☑ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Distributors and Clinics		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:** N/A

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attachment A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New Jersey

Parent Company (if any): GC Biopharma Corp.

Corporation/Organization Name: GC Biopharma USA, Inc.

Mailing Address: 500 Frank W. Burr Blvd., Suite 230, Mailbox #48

City: Teaneck State: NJ Zip: 07666

Telephone: (201) 592-0561 Email: state@gcbiopharmausa.com

Contact Person Name: Brian Kelly

N/A

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
N/A 1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration See Attachment A 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment G		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment B	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment B		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment C	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment D		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A-See Attachment B		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment E	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment F	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf. N/A - See Attachment A		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form at:** http://bop.nv.gov/Services/newapps/Business/. N/A - See Attachment A		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

GC Biopharma USA, Inc.

Facility Name

Brian Kelly

Print Name of Authorized Person Submitting Application

B. Kelly

Original signature of Authorized Person (copies or stamps not accepted)

6/8/26

Date

Board Use Only	Date Received: 6/9/26	Amount: $1000.00

Attachment A

Nature of Business and FDA Registration

GC Biopharma USA, Inc. will operate as a virtual drug manufacturer and will only distribute products bearing the labeler code for its parent company, GC Biopharma Corp. GC Biopharma USA, Inc. appears on the product label as the entity "distributed by." Because it will exclusively distribute prescription drugs manufactured by a single manufacturer, GC Biopharma USA, Inc. is exempt from submitting fingerprint cards and qualifies for the $25,000 surety bond / means of security under Nevada law, pursuant to NAC 639.593(6)(e). The company will not handle prescription drugs at its business office. A facility owned and operated by the parent company will be used to manufacture the product and third party will be used to distribute. Provided below is the contact information for the manufacturing facility and the third party logistics provider that will be used to ship the product. Enclosed is proof of the parent company's FDA labeler code and a copy of the product label.

Manufacturing Facility:

GC Biopharma Corp.
586, Gwahaksaneop 2-ro, Ochang-eup, Cheongwon-gu, Cheongju, Chungcheongbuk-do 28119, Korea, South (KOR)
FDA Establishment #: 3009561235

Third Party Logistics Provider:

Integrated Commercialization Services, LLC
420 International Drive, Suite 500
Brooks, KY 40109

/ NDC (index.cfm)

National Drug Code Directory

Current through February 19, 2026

You have searched Finished drug products

Search Results: *'GC Bio'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 **records per page**

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
Alyglo	61476-104-05	100 mg/mL	LIQUID	INTRAVENOUS	BLA125743	GC Biopharma Corp.	61476-104	Human immunoglobulin G	HUMAN IMMUNOGLOBULIN G	PLASMA DERIVATIVE	12/15/2023	N/A	BLA	1 VIAL, GLASS in 1 CARTON (61476-104-05) / 50 mL in 1 VIAL, GLASS (61476-104-01)	Antigen Neutralization [MoA], Human Immunoglobulin G [EPC], Immunoglobulins [CS], Passively Acquired Immunity [PE]
Alyglo	61476-104-10	100 mg/mL	LIQUID	INTRAVENOUS	BLA125743	GC Biopharma Corp.	61476-104	Human immunoglobulin G	HUMAN IMMUNOGLOBULIN G	PLASMA DERIVATIVE	12/15/2023	N/A	BLA	1 VIAL, GLASS in 1 CARTON (61476-104-10) / 100 mL in 1 VIAL, GLASS (61476-104-02)	Antigen Neutralization [MoA], Human Immunoglobulin G [EPC], Immunoglobulins [CS], Passively Acquired Immunity [PE]
Alyglo	61476-104-20	100 mg/mL	LIQUID	INTRAVENOUS	BLA125743	GC Biopharma Corp.	61476-104	Human immunoglobulin G	HUMAN IMMUNOGLOBULIN G	PLASMA DERIVATIVE	12/15/2023	N/A	BLA	1 VIAL, GLASS in 1 CARTON (61476-104-20) / 200 mL in 1 VIAL, GLASS (61476-104-03)	Antigen Neutralization [MoA], Human Immunoglobulin G [EPC], Immunoglobulins [CS], Passively Acquired Immunity [PE]

Showing 1 to 3 of 3 entries Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Attachment B

Corporation Information

GC Biopharma USA, Inc.
500 Frank W. Burr Blvd., Suite 230, Mailbox #48
Teaneck, NJ 07666

GC Biopharma UA, Inc. is a wholly owned subsidiary of GC Biopharma Corp., a publicly traded company located at 107 Ihyeon-ro 30-beongil, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea.

Corporate Officers:

Woo Jin Lee
CEO

Jaewk Seo
Treasurer

Lisa M. Betts
Secretary

The corporate officers may be reached at the above address.

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
LONG FORM STANDING WITH OFFICERS AND DIRECTORS

GC BIOPHARMA USA, INC.
0101042128

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on August 29, 2016.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

C T CORPORATION SYSTEM
820 BEAR TAVERN ROAD
WEST TRENTON, NJ 08628

I further certify that as of the date of this certificate, the following were listed as officers/directors of this business on the last Annual Report filed in this office on October 04, 2025.

CHIEF EXEC. OFFICER (CEO)	*WOO JIN LEE* *500 FRANK W. BURR BLVD* *STE 230* *TEANECK, NJ 07666*
SECRETARY	*LISA BETTS* *500 FRANK W. BURR BLVD* *STE 230* *TEANECK, NJ 07666*
TREASURER	*JAEWK SEO* *500 W FRANK W. BURR BLVD* *STE 230* *TEANECK, NJ 07666*

Continued on next page...

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE

0022561

P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written noticeprior to the change of the address of such new location and the name and address of the individual to be in charge thereof.A fee of $20.00 shall accompanying such notification,"

Registered as: ☑ Manufacturer ☑ Distributor which conducts business at the following locations:

Reg. No.:
5005463

GC BIOPHARMA USA, INC.
500 FRANK W. BURR BLVD STE 230
TEANECK, NJ 07666

ISSUED PURSUANT TO:
N.J.S.A. 24:6B
EXPIRES: January 31, 2027

Establishment Copy

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 101075153

Application/License No. _____

GC BIOPHARMA USA, INC. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 500 FRANK W BURR BLVD SUITE 230 48 TEANECK, NJ, 07666 (Address of Applicant/Principal), as PRINCIPAL, and U.S. SPECIALTY INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of Texas (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 801 S. Figueroa Street, Suite 700, Los Angeles, CA 90017 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 6/3/2026 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 3rd day of June, 2026.

APPLICANT/PRINCIPAL

GC BIOPHARMA USA, INC.

Authorized Representative

SURETY

U.S. SPECIALTY INSURANCE COMPANY

Surety Company's Representative

LAWRENCE F. MCMAHON, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

CALIFORNIA ALL-PURPOSE ACKNOWLEDGMENT

Civil Code § 1189

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document, to which this certificate is attached, and not the truthfulness, accuracy or validity of that document.

STATE OF CALIFORNIA

County of San Diego }

On June 03, 2026 (Date) before me, Lilia De Loera (Insert Name of Notary exactly as it appears on the official seal), Notary Public,

personally appeared Lawrence F. McMahon (Name(s) of Signer(s))

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

Witness my hand and official seal.

Signature _____ (Signature of Notary Public) Lilia De Loera

LILIA DE LOERA
Notary Public - California
San Diego County
Commission # 2547485
My Comm. Expires Feb 16, 2030

Place Notary Seal Above

OPTIONAL

Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of the form to another document.

Description of Attached Document

Title or Type of Document: _____

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

Capacity(ies) Claimed by Signer(s)

Signer's Name: _____

☐ Individual
☐ Corporate Officer — Title(s): _____
☐ Partner ☐ Limited ☐ General
☑ Attorney in Fact
☐ Trustee
☐ Guardian or Conservator
☐ Other: _____

Signer is Representing:
Surety Company

RIGHT THUMBPRINT OF SIGNER
Top of thumb here

Signer's Name: _____

☐ Individual
☐ Corporate Officer — Title(s): _____
☐ Partner ☐ Limited ☐ General
☐ Attorney in Fact
☐ Trustee
☐ Guardian or Conservator
☐ Other: _____

Signer is Representing:

RIGHT THUMBPRINT OF SIGNER
Top of thumb here

TOKIO MARINE HCC

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS:

That, U.S. SPECIALTY INSURANCE COMPANY (the "Company"), a corporation duly organized and existing under the laws of the State of Texas, and having its principal office in Houston, Harris County, Texas, does by these presents make, constitute and appoint,

LAWRENCE F. MCMAHON

its true and lawful Attorney-in-Fact, with full power and authority hereby conferred in its name, place and stead, to execute, acknowledge and deliver any and all bonds, recognizances, undertakings or other instruments or contracts of suretyship to include riders, amendments, and consents of surety regarding bond number 101075153, providing the bond penalty does not exceed Twenty-five thousand and 00/100 Dollars ($25,000.00). Said appointment is made under and by authority of the following resolutions of the Board of Directors of U. S. Specialty Insurance Company:

"Be it Resolved, that the President, any Vice-President, any Assistant Vice-President, any Secretary or any Assistant Secretary shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

Attorney-in-Fact may be given full power and authority for and in the name of and on behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements or indemnity and other conditional or obligatory undertakings, including any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts, and any and all notices and documents canceling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be binding upon the Company as if signed by the President and sealed and effected by the Corporate Secretary.

Be it Resolved, that the signature of any authorized officer and seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signature or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached." Adopted by unanimous written consent in lieu of meeting on September 1st, 2011.

The Attorney-in-Fact named above may be an agent or a broker of the Company. The granting of this Power of Attorney is specific to this bond and does not indicate whether the Attorney-in-Fact is or is not an appointed agent of the Company.

IN WITNESS WHEREOF, U.S. Specialty Insurance Company has caused its seal to be affixed hereto and executed by its Senior Vice President on this 20th day of November, 2024.

U.S. SPECIALTY INSURANCE COMPANY

By: _____
Adam S. Pessin, Senior Vice President

A Notary Public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

On this 20th day of November, 2024, before me, D. Littlefield, a notary public, personally appeared Adam S. Pessin, Senior Vice President of U.S. Specialty Insurance Company, who proved to me on the basis of satisfactory evidence, to be the person whose name is subscribed to the within instrument and acknowledged to me that he executed the same in his authorized capacity, and that by his signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of CALIFORNIA that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Signature _____ (seal)

D. LITTLEFIELD
Notary Public - California
Los Angeles County
Commission # 2476570
My Comm. Expires Jan 31, 2028

I, Kio Lo, Assistant Secretary of U.S. Specialty Insurance Company, do hereby certify that the Power of Attorney and the resolution adopted by the Board of Directors of said Company as set forth above, are true and correct transcripts thereof and that neither the said Power of Attorney nor the resolution have been revoked and they are now in full force and effect.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seals of said Companies at Los Angeles, California this 3rd day of June, 2026.

Bond No. 101075153
Agency No. 2036

Kio Lo, Assistant Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler GC Biopharma USA, Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 500 Frank W. Burr Blvd., Suite 230, Mailbox #48

City Teaneck State NJ Zip 07666

Mailing Address (if different from physical address) Same as physical address

City _____ State _____ Zip _____

Telephone (201) 592-0561 Website www.gcbiopharma.us

Licensing Company Email state@gcbiopharmausa.com

Section 2: Personal Information

First Brian Middle _____ Last Kelly

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 500 Frank W. Burr Blvd., Suite 230, Mailbox #48

City Teaneck State NJ Zip 07666

Telephone (201) 592-0560 Email state@gcbiopharmausa.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Seton Hall University		9/1995 - 5/2000	
Address: 400 S. Orange Avenue	City: South Orange	State: NJ	Zip: 07079
Diploma/Degree obtained, if any: Bachelor's degree			

School Name		From - To (MM/YY – MM/YY)	
Boonton High School		9/91 - 6/95	
Address: 306 Lathrop Avenue	City: Boonton	State: NJ	Zip: 07005
Diploma/Degree obtained, if any: High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2021-present	[redacted]	Boonton	NJ	[redacted]
2020-2021		Mountain Lakes	NJ	
2014-2020		Newton	NJ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)
GC Biopharma USA, Inc		07/01/25 - present
Business Address	City / State / Zip	
500 Frank W. Burr Blvd., Suite 230, Mailbox #48	Teaneck / NJ / 07666	
Phone	Title	Number of Employed Hours
(201) 592-0561	Head of Market Access	~2,100

Description of Duties:
Oversee commercial distribution of Rx products through distributors, specialty pharmacies, while managing product flow and inventory requirements, chargebacks, pricing and contracting, and associated record-keeping requirements.

Business Name		From - To (MM/YY – MM/YY)
Octapharma USA		11/01/21 - 6/15/25
Business Address	City / State / Zip	
Octapharma USA	Paramus / NJ / 07652	
Phone	Title	Number of Employed Hours
201-604-1130	Head of Market Access	~6,800

Description of Duties:
Oversee commercial product pull-through and utilization on payer channels. While managing chargebacks, pricing and contracting, and associated record-keeping requirements.

Business Name		From - To (MM/YY – MM/YY)
Business Address	City / State / Zip	
Phone	Title	Number of Employed Hours

Description of Duties:

Business Name		From - To (MM/YY – MM/YY)
Business Address	City / State / Zip	
Phone	Title	Number of Employed Hours

Description of Duties:

Business Name		From - To (MM/YY – MM/YY)
Business Address	City / State / Zip	
Phone	Title	Number of Employed Hours

Description of Duties:

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Brian Kelly, **certify that as the designated representative for**

GC Biopharma USA, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BK I am at least 21 years of age;
3. BK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Brian Kelly

Print Name (First, Last)

B Kelly

Original Signature (electronic, copies or stamps not accepted)

6/8/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brian Kelly

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/8/26

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Bergen

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/8/26

Date

Subscribed and Sworn to before me this 8th day of June.

Notary Public Signature

TAHMEDA MUNIM
NOTARY PUBLIC
STATE OF NEW JERSEY
MY COMMISSION EXPIRES NOVEMBER 7, 2029
COMMISSION: #50227614

TAHMEDA MUNIM My Comm. Expires NOTARY PUBLIC November 7, 2029 NEW JERSEY (Seal)

GCBP USA, Inc - List of employees as of 04/30/2026

Work State	Last Name	First Name	Count
AL	Watson	Jonathan	1
AZ	Jones	Pamela	1
CA	Alejandre	Theodore	1
	Huber	Alan	1
	Martin	Kristen	1
	Moll	Stephen	1
FL	Manning	Debbie	1
	Perez	Alejandro	1
IL	Betts	Lisa	1
KY	Ragan	Brian	1
MD	Kpetigo	Abla	1
MI	Utrup	Michelle	1
MN	Miller	Katherine	1
	Ness	Stacey	1
MO	Remy-Mart	Laura	1
	Schomburg	Sheri	1
NJ	Sun	Ilwon	1
	Camacho	Ricardo	1
	Centeno	Haymara	1
	Huh	Jung	1
	Iskandar	Christina	1
	Kelly	Brian	1
	Kim	Yeohyun	1
	LIEBHAUSE	DAVID	1
	Munim	Tahmeda	1
	Sarfin	Michele	1
	Seo	Jaewk	1
	Zam	Sean	1
NV	Avila	Shelly	1
OH	Musselmar	Kea	1
PA	Nash	Steven	1
	Quince	Misty	1
TX	Storr	Dexter	1
UT	Strasters	Suzanne	1
Grand Total			**34**

U.S. License No. 2033

Distributed by:

GC Biopharma USA, Inc.
500 Frank W. Burr Boulevard,
Teaneck, NJ 07666, USA

PRINCIPAL DISPLAY PANEL

NDC 61476-104-01
immune globulin intravenous,
human-stwk)
ALYGLO
10% Liquid



PRINCIPAL DISPLAY PANEL

NDC 61476-104-05
immune globulin intravenous,
human-stwk)
ALYGLO
10% Liquid



PRINCIPAL DISPLAY PANEL

NDC 61476-104-02

immune globulin intravenous, human-stwk)

ALYGLO

10% Liquid



PRINCIPAL DISPLAY PANEL

NDC 61476-104-10

immune globulin intravenous, human-stwk)

ALYGLO

10% Liquid



PRINCIPAL DISPLAY PANEL

NDC 61476-104-03

immune globulin intravenous, human-stwk)

ALYGLO

10% Liquid



PRINCIPAL DISPLAY PANEL

NDC 61476-104-20

immune globulin intravenous,

human-stwk)

ALYGLO

10% Liquid



ALYGLO
human immunoglobulin g liquid

Product Information			
Product Type	PLASMA DERIVATIVE	**Item Code (Source)**	NDC:61476-104
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Human immunoglobulin G (UNII: 66Y330CJHS) (Human immunoglobulin G - UNII:66Y330CJHS)	Human immunoglobulin G	100 mg in 1 mL

Inactive Ingredients

4HH

Removed from Consent Agenda

411

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
☐ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: [redacted]
	☑ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			■ Long Term Care
	* Current license #: PH 0279		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	■ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: AHCS Well Care, LLC dba AHCS Patient Care Pharmacy

Physical Address: 4101 Wagon Trail Ave

City: Las Vegas State: NV Zip: 89118

Mailing Address (if different from physical address): PO Box 3055

City: Huntington Beach State: CA Zip: 92605

Telephone: (702) 576-9545 Toll Free # (NAC 639.708, NRS 639.23286): N/A

Fax: (702) 946-0353 Contact Email: compliance@ahcspharmacy.com

Website: https://ahcspharmacy.com/

Nevada Business License # (if applicable) NV20243145577

Supervising/Managing Pharmacist Name (NRS 639.220): Vy Burns

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19369

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Vy Burns	NV Pharmacist Registration #: 19369
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): Advantage HCS, LLC

Corporation/Organization Name: AHCS Well Care, LLC

Mailing Address: PO Box 3055

City: Huntington Beach State: CA Zip: 92605

Telephone: (714) 706-9030 Email: compliance@ahcspharmacy.com

Contact Person Name: Thomas Lam

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ■ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO (title) for AHCS Patient Care Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Michael Zeglinski

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

8/24/2026

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Michael Zeglinski hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO (title) for AHCS Patient Care Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

_____
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

_____
Notary Public

See attached California jurat certificate

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Orange

Subscribed and sworn to (or affirmed) before me on this 24th day of August, 2026, by Michael Zeglinski, proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

JEWEL Y. CABIGAS
COMM. #2548069
NOTARY PUBLIC-CALIFORNIA
ORANGE COUNTY
My Comm. Expires Feb. 17, 2030

(Seal)

Signature

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Vy Burns Pharmacist Registration #: 19369

Pharmacy Name: AHCS Well Care, LLC dba AHCS Patient Care Pharmacy

Initial each statement below to indicate you have read and agree with the following:

VB — I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

VB — I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

VB — I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

VB — I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

VB — I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		V
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		V
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		V
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		V

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

8/24/26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Zeglinski

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

8/24/2026

Date

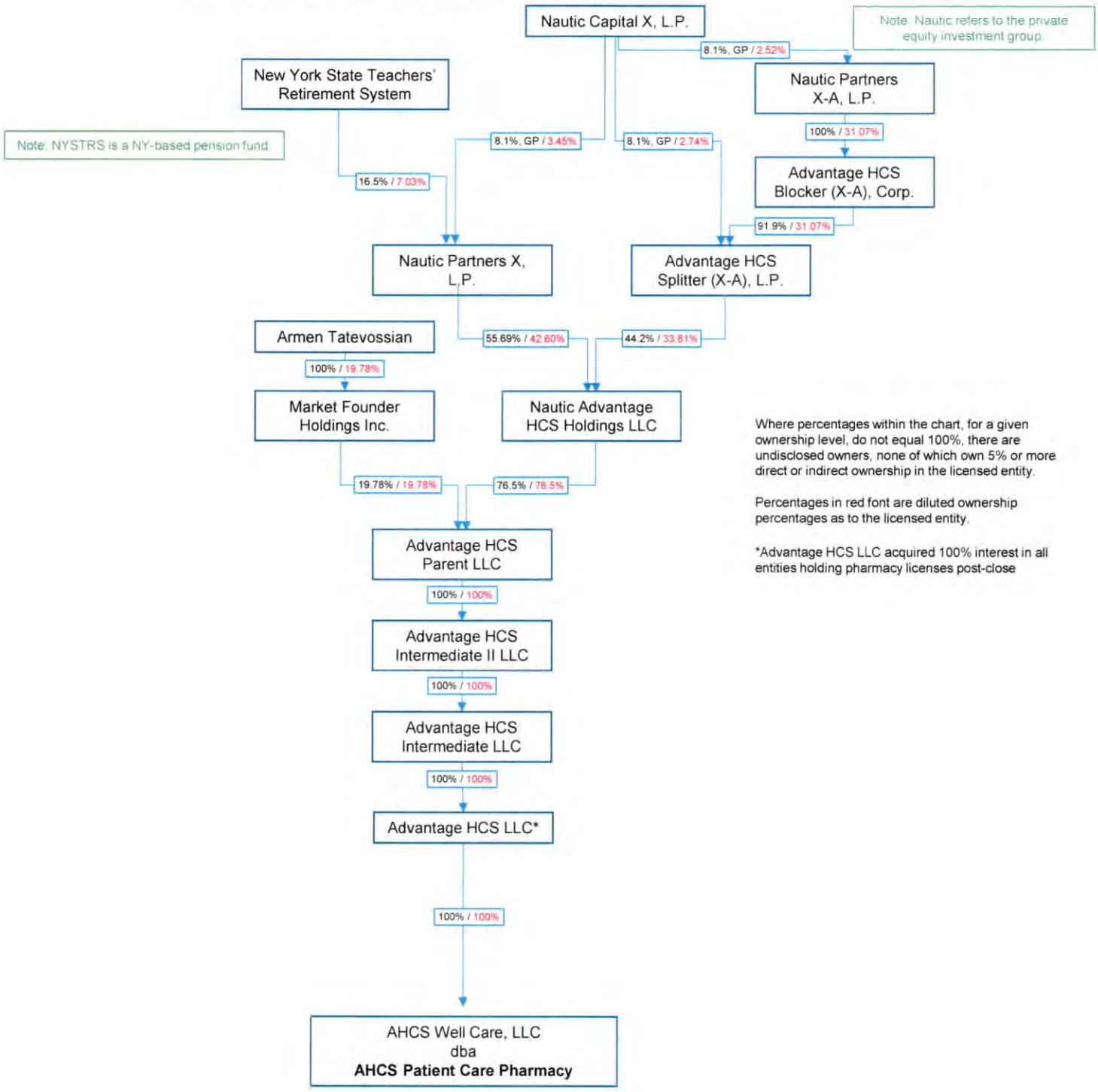
Board Use Only	Date Received: 8/27/26	Amount: $500 ch 4670

AHCS Well Care, LLC dba AHCS Patient Care Pharmacy

Officer List

Entity	DBA	Officers
AHCS Well Care, LLC, a Nevada limited liability company	AHCS Patient Care Pharmacy	• Michael Zeglinski - CEO • Artin Dembekjian – SVP of Pharmacy Operations • Ryan Jenson - CFO and Treasurer

Post-Close Organizational Chart



Where percentages within the chart, for a given ownership level, do not equal 100%, there are undisclosed owners, none of which own 5% or more direct or indirect ownership in the licensed entity.

Percentages in red font are diluted ownership percentages as to the licensed entity.

*Advantage HCS LLC acquired 100% interest in all entities holding pharmacy licenses post-close

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **AHCS Well Care, LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 06/21/2024, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 08/19/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202608196902923
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: AHCS Well Care, LLC dba AHCS Patient Care Pharmacy
Pharmacy/Wholesaler License # (if applicable): Pending
Physical Address: 4101 Wagon Trail Ave
City: Las Vegas State: NV Zip: 89118
Mailing Address (if different from physical address): PO Box 3055
City: Huntington Beach State: CA Zip: 92605
Telephone: 702-576-9545 Website: www.ahcspharmacy.com
Licensing Company Email: compliance@ahcspharmacy.com

Section 2: Personal Information

First: Vy Middle: – Last: Burns
Alias(es, nicknames, name changes, etc.): –
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X
Mailing Address: [redacted]
City: Las Vegas State: NV Zip: [redacted]
Telephone: [redacted] Email: [redacted]
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Roseman University			09/13 – 05/16	
Address		**City**	**State**	**Zip**
11 Sunset Way		Henderson	NV	89014
Diploma/Degree obtained, if any				
PharmD				
School Name			**From - To (MM/YY – MM/YY)**	
College of Southern Nevada			09/08 – 05/13	
Address		**City**	**State**	**Zip**
6375 W Charleston Blvd		Las Vegas	NV	89146
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY)**	
Nguyen Chi Thanh			09/04 – 05/17	
Address		**City**	**State**	**Zip**
Vietnam				
Diploma/Degree obtained, if any				
High school Diploma				
School Name			**From - To (MM/YY – MM/YY)**	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY**	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/17 – now	[redacted]	Las Vegas	NV	[redacted]
07/12 – 08/17	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Patient Care Pharmacy			04/19 - now
Business Address	**City**	**State**	**Zip**
4101 Wagon Trail Ave	Las Vegas	NV	89118
Phone	**Title**	**Number of Employed Hours**	
702 576 9545	Pharmacy Manager	15980	
Description of Duties			
oversee pharmacy operations			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		V
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		V
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		V
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		V
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		V
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		V
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		V
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		V
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		V
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		V

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8/24/26
Date

I, Vy Burns, **certify that as the designated representative for**

Patient Care Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. VB I am at least 21 years of age;
3. VB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. VB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. VB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. VB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. VB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

VY BURNS

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/24/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

VY, BURNS

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/24/26

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, VY ANH BURNS, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/24/26

Date

Subscribed and Sworn to before me this 24th day of AUG 2026.

Notary Public Signature

KENNETH ALBERT RIZO HERNANDEZ
Notary Public - State of Nevada
Appt. No. 23-6534-01
My Appt. Expires 10-29-2027

(Seal)

4JJ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada ☐ Out-of-Nevada	■ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ■ Other: Free Standing Emergency Department	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ■ Other: Emergency Department

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	■ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	■ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	■ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	■ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: ER of Southern Highlands

Physical Address: 4220 W. Cactus Ave

City: Las Vegas State: NV Zip: 89141

Mailing Address (if different from physical address): 1155 Raiders Way

City: Henderson State: NV Zip: 89052

Telephone: 725-235-2260 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 725-235-2261 Contact Email: cuong.khong@uhsinc.com

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Cuong Khong

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20743

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Cuong Khong	NV Pharmacist Registration #: 20743
Name: Robin Bonga	NV Pharmacist Registration #: 15598
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: DELAWARE

Parent Company (if any): UNIVERSAL HEALTH SERVICES, INC

Corporation Name: ER OF SOUTHERN HIGHLANDS

Mailing Address: 367 SOUTH GULPH ROAD

City: KING OF PRUSSIA State: PA Zip: 19406-0958

Telephone: 610-768-3300 Email: uhscorpfilings@uhsinc.com

Contact Person Name: STEVE FILTON

Date of SEC Registration: 1981	SEC Registration Number: 1-10765	Stock Exchange Symbol: UHS

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☑ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Authorized Person (title) for ER of Southern Highlands (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

STEVE FILTON

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

8/27/2026

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Cuong Khong hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Managing Pharmacist (title) for ER of Southern Highlands (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 28 day of August, 2026

Notary Public

Talia Attolico
Notary Public - State of Nevada
County of Clark
APPT. NO. 23-3387-01
My Appt. Expires: Oct. 20, 2027

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Cuong Khong Pharmacist Registration #: 20743

Pharmacy Name: ER of Southern Highlands

Initial each statement below to indicate you have read and agree with the following:

CK I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

CK I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

CK I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

CK I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

CK I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

8/28/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

STEVE FILTON

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

8/27/2026

Date

Board Use Only	Date Received: 8/31/26	Amount: $500.00

UNIVERSAL HEALTH SERVICES, INC.
OFFICERS, BOARD OF DIRECTORS
AND TOP FOUR STOCKHOLDERS

- **Officers:**
  - Alan B. Miller – Founder and Executive Chairman of the Board
  - Marc D. Miller – President and Chief Executive Officer
  - Steve G. Filton – Executive Vice President and Chief Financial Officer
  - Edward H. Sim – Executive Vice President and President, Acute Care Division
  - Charles F. Boyle – Senior Vice President and Controller
  - Jim Clark – Senior Vice President, Finance, Acute Care Division
  - Thomas Day – Senior Vice President, Finance, Behavioral Health Division
  - Matthew D. Klein – Senior Vice President and General Counsel
  - Michael S. Nelson – Senior Vice President, Strategic Services
  - Cheryl K. Ramagano – Senior Vice President and Treasurer
  - Maria Zangardi – Senior Vice President, Human Resources

- **Board of Directors:**
  - Alan B. Miller
  - Marc D. Miller
  - Nina Chen
  - Eileen C. McDonnell
  - Warren J. Nimetz
  - Maria Singer
  - Elliot J. Sussman, MD

- **Top Four Stockholders:**
  - Alan B. Miller – 13.0%
  - First Eagle Investment Management – 8.6%
  - BlackRock, Inc. – 7.7%
  - Marc D. Miller – 4.0%

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "UNIVERSAL HEALTH SERVICES, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SIXTH DAY OF AUGUST, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "UNIVERSAL HEALTH SERVICES, INC." WAS INCORPORATED ON THE EIGHTH DAY OF JANUARY, A.D. 1979.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

865562 8300

SR# 20264203147

Authentication: 204945853

Date: 08-26-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

1983

CERTIFICATE OF INCORPORATION

OF

UNIVERSAL HEALTH SERVICES, INC.

1. The name of the corporation is Universal Health Services, Inc.

2. The address of its registered office in the State of Delaware is No. 100 West Tenth Street, in the City of Wilmington, County of New Castle. The name of its registered agent at such address is The Corporation Trust Company.

3. The nature of the business or purposes to be conducted or promoted is:

To engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware.

4. The total number of shares of all classes of capital stock which the corporation shall have authority to issue is Three Million (3,000,000), all of which shares shall be shares of Common Stock and the par value of each of such shares is One Cent ($.01) amounting in the aggregate to Thirty Thousand Dollars ($30,000).

5. The name and mailing address of each incorporator is as follows:

NAME	MAILING ADDRESS
Roy B. Simpson, Jr.	Reavis & McGrath 345 Park Avenue New York, New York 10022

6. The corporation is to have perpetual existence.

00002

7. In furtherance and not in limitation of the powers conferred by statute, the board of directors is expressly authorized: To make, alter or repeal the by-laws of the corporation.

8. Meetings of stockholders may be held within or without the State of Delaware, as the by-laws may provide. The books of the corporation may be kept (subject to any provisions contained in the statutes) outside the State of Delaware at such place or places as may be designated from time to time by the board of directors or in the by-laws of the corporation. Elections of directors need not be by written ballot unless the by-laws of the corporation shall so provide.

9. Whenever a compromise or arrangement is proposed between this corporation and its creditors or any class of them and/or between this corporation and its stockholders or any class of them, any court of equitable jurisdiction within the State of Delaware may, on the application in a summary way of this corporation or of any creditors or stockholders thereof or on the application of any receiver or receivers appointed for this corporation under the provisions of Section 291 of Title 8 of the Delaware Code or on the application of trustees in dissolution or of any receiver or receivers appointed for this corporation under the provisions of Section 279 of Title 8 of the Delaware Code order a meeting of the creditors or class of creditors, and/or of the stockholders or class of stockholders of this corporation, as the case may be, to be summoned in such

manner as the said court directs. If a majority in number representing three-fourths in value of the creditors or class of creditors, and/or of the stockholders or class of stockholders of this corporation, as the case may be, agree to any compromise or arrangement and to any reorganization of this corporation as a consequence of such compromise or arrangement, the said compromise or arrangement and the said reorganization shall, if sanctioned by the court to which the said application has been made, be binding on all the creditors or class of creditors, and/or on all the stockholders or class of stockholders, of this corporation, as the case may be, and also on this corporation.

10. The corporation reserves the right to amend, alter, change or repeal any provisions contained in this certificate of incorporation, in the manner now or hereafter prescribed by statute, and all rights conferred upon stockholders herein are granted subject to this reservation.

THE UNDERSIGNED, being the sole incorporator hereinbefore named, for the purpose of forming a corporation pursuant to the General Corporation Law of the State of Delaware, does make this certificate, hereby declaring and certifying that this is his act and deed and the facts herein stated are true, and accordingly has hereunto set his hand this 5th day of January, 1979.



00004

4KK

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: TBD
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	■ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	■ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	■ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Kaiser Permanente Fifth Street Pharmacy

Physical Address: 803 West 5th Street

City: Reno State: NV Zip: 89503-4311

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 775-678-4101 Toll Free # (NAC 639.708, NRS 639.23286): 855-937-5768

Fax: 775-678-4103 Contact Email: co-pharmacy.compliance@kp.org

Website: www.kp.org

Nevada Business License # (if applicable) NV20253425062

Supervising/Managing Pharmacist Name (NRS 639.220): Christine Lo

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24380

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Christine Lo	NV Pharmacist Registration #: 24380
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): Kaiser Foundation Health Plan, Inc. (50.1%); Renown Health (49.9%)

Corporation/Organization Name: HPNV Holdco, Inc.

Mailing Address: 10315 Professional Circle

City: Reno State: Nevada Zip: 89521

Telephone: 916-842-0298 Email: Patricia.M.Rodriguez@kp.org

Contact Person Name: Patricia Rodriguez

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Chief Executive Officer (title) for Kaiser Permanente Fifth Street Pharmac (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Patricia Rodriguez

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

8/18/26

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Patricia Rodriguez hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Chief Executive Officer (title) for Kaiser Permanente Fifth Street Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 18 day of August, 2026

Notary Public

JOANNE TAPIA
Notary Public - State of Nevada
Appointment No. 15-2499-2
My Appointment Expires 04/14/2029

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Christine Lo Pharmacist Registration #: 24380

Pharmacy Name: Kaiser Permanente Fifth Street Pharmacy

Initial each statement below to indicate you have read and agree with the following:

CL I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

CL I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

CL I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

CL I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

CL I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

8/14/26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Patricia Rodriguez

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

3/19/26

Date

Board Use Only	Date Received: 3/26	Amount: $600

HPNV Holdco, Inc.
Directors and Officers

Officers

Name	Title	Address
Patricia Rodriguez	Chief Executive Officer	10315 Professional Circle, Reno, NV 89521
Vanessa Benavides	Secretary	One Kaiser Plaza, Oakland, CA 94612
Thomas Meier	Treasurer	One Kaiser Plaza, Oakland, CA 94612
Maryann Bodayle	Asst. Sec.	One Kaiser Plaza, Oakland, CA 94612
Christina Lockwood	Asst. Sec.	One Kaiser Plaza, Oakland, CA 94612

Directors

Name	Title	Address
Samuel Glick	Director, Chair	One Kaiser Plaza, Oakland, CA 94612
Charles Bevilacqua	Director	One Kaiser Plaza, Oakland, CA 94612
Alfonse Upshaw	Director	One Kaiser Plaza, Oakland, CA 94612
Jeffrey Krawcek	Director	One Kaiser Plaza, Oakland, CA 94612
Brian Erling	Director	10315 Professional Circle, Reno, NV 89521
Anna Loomis	Director	10315 Professional Circle, Reno, NV 89521
Rahul Mediwala	Director	10315 Professional Circle, Reno, NV 89521

Corporate Information:

HPNV Holdco, Inc.
Address: 10315 Professional Circle, Reno, NV 89521

Ownership Information:

Kaiser Foundation Health Plan, Inc.
Address: One Kaiser Plaza, Oakland, CA 94612
Ownership of HPNV Holdco, Inc.: 50.1%

Renown Health
Address: 10315 Professional Circle, Reno, NV 89521
Ownership of HPNV Holdco, Inc.: 49.9%

STOCKHOLDER INFORMATION

There are no stockholders to report.

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **HPNV HoldCo, Inc.** as a DOMESTIC NONPROFIT CORPORATION (82) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 08/26/2025, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 05/15/2026.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202605156684145
You may verify this certificate online at https://www.nvsilverflume.gov/home

KAISER PERMANENTE

August 18, 2026

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

To Whom it May Concern:

Attached is a chart summarizing our supplemental responses to Section 3, Question 3 of the pharmacy license application for Kaiser Permanente Fifth Street Pharmacy. Copies of the documents for each entry will be sent via Secure File Transfer (SFT). We have included responsive items for the parent companies of HPNV HoldCo, Inc, which are Kaiser Foundation Health Plan, Inc., and Renown Health. These responses have been compiled to the best of our knowledge with reasonable diligence.

Regards,

Patricia Rodriguez
Chief Executive Officer
10315 Professional Circle
Reno, NV 89521

License #	License Name	Date	Agency / Case	Action
PHY 43518	Kaiser Health Plan Manteca PHY 491	4/19/2013	CA Board of Pharmacy, CI 2010-48794	Citation
PHY 43518	Kaiser Health Plan Manteca PHY 491	5/2/2013	CA Board of Pharmacy, CI 2011-51585	Letter of Admonishment
PHY 46987	Kaiser Permanente Pharmacy #431	7/8/2013	CA Board of Pharmacy, CI 2011-51929	Citation and Fine
PHY 41612	Kaiser Permanente Pharmacy #985	2015	CA Board of Pharmacy, CI 2015-69738	Citation and Fine
PHY 51709	Kaiser Permanente Pharmacy #607	3/29/2016	CA Board of Pharmacy, CI 2015-69670	Citation
PHY 50985	Kaiser Permanente Pharmacy #610	5/20/2016	CA Board of Pharmacy, CI 2015-70429	Citation and Fine
PHY 46384	Kaiser Permanente Pharmacy #833	11/28/2016	CA Board of Pharmacy, AC201500553300	Revocation Stayed (Probation Completed 01-May-2020)
PHY 37029	Kaiser Permanente Pharmacy #113	11/1/2017	CA Board of Pharmacy, AC201500580600	Revocation Stayed (Probation Completed 31-Oct-2020)
PHY 37047	Kaiser Health Plan MOB 1 PHY 211	11/17/2017	CA Board of Pharmacy, CI 2017-77550	Letter of Admonishment
PHY 43294	Kaiser Health Plan MOB PHY 401	1/23/2018	CA Board of Pharmacy, CI 2016-74415	Citation and Fine
PHY 47092	Kaiser Permanente Pharmacy #215	2/26/2018	CA Board of Pharmacy, CI 2015-66539	Letter of Admonishment Upheld
PHY 37446	Kaiser Health Plan 1 New PHY 601	3/2/2018	CA Board of Pharmacy, CI 2017-76653	Citation
PHY 41612	Kaiser Permanente Pharmacy #985	4/30/2018	CA Board of Pharmacy, CI 2016-74300	Citation and Fine
PHY 41612	Kaiser Permanente Pharmacy #985	5/15/2018	CA Board of Pharmacy, CI 2016-74548	Citation
PHY 49886	Kaiser Permanente Pharmacy #249	9/10/2019	CA Board of Pharmacy, AC201700631700	Stipulated Settlement and Disciplinary Order
PHY 43605	Kaiser Health Plan Two North PHY 637	10/17/2019	CA Board of Pharmacy, CI 2018-81807	Citation
PHY 51636	Kaiser Permanente Pharmacy #105	12/12/2019	CA Board of Pharmacy, CI 2018-82283	Citation & Fine with Order of Abatement
PHY 37411	Kaiser Health Plan C PHY 723	5/5/2020	CA Board of Pharmacy, CI 2019-87818	Citation
PHY 37410	Kaiser Health Plan B PHY 722	5/5/2020	CA Board of Pharmacy, CI 2019-87820	Citation
PHY 51530	Kaiser Permanente Pharmacy #264	10/15/2020	CA Board of Pharmacy, CI 2018-84390	Citation
LSC 100395	Kaiser Permanente Pharmacy #377 (permanently closed)	1/11/2021	CA Board of Pharmacy, CI 2019-86808	Citation & Fine with Order of Abatement
PHY 40642	Kaiser Health Plan MOB 1 PHY 511	5/5/2021	CA Board of Pharmacy, CI 2019-88682	Letter of Admonishment
PHY 41612	Kaiser Permanente Pharmacy #985	9/24/2021	CA Division of Occupational Safety & Health, 950635	Citation and Notification of Penalty
PHY 36679	Kaiser Health Plan South 1 PHY 471	12/15/2021	CA Board of Pharmacy, CI 2020-92090	Letter of Admonishment
PHY 56090	Kaiser Permanente Pharmacy #971	6/22/2022	CA Board of Pharmacy, CI 2021-93681	Letter of Admonishment

License #	License Name	Date	Agency / Case	Action
PHY 30218	Kaiser Permanente Pharmacy #014	9/16/2022	CA Board of Pharmacy, CI 2021-94164	Citation
PHY 40642	Kaiser Health Plan MOB 1 PHY 511	11/18/2022	CA Board of Pharmacy, CI 2021-95786	Citation and Fine
PHY 42151	Kaiser Foundation CPP Pharmacy 251	12/28/2022	CA Board of Pharmacy, CI 2021-94830	Citation and Fine
PHY 50836	Kaiser Permanente Pharmacy #596	2/28/2023	CA Board of Pharmacy, CI 2021-95125	Citation and Fine
PHY 39805	Kaiser Permanente Pharmacy #197	7/14/2023	CA Board of Pharmacy, CI 2022-97475	Citation and Fine
PHY 49285	Kaiser Permanente Pharmacy #266	8/8/2023	CA Board of Pharmacy, CI 2021-95658	Citation and Fine
PHY 37446	Kaiser Health Plan 1 New PHY 601	10/6/2023	CA Board of Pharmacy, CI 2022-100594	Citation and Fine
PHY 43312	Kaiser Permanente Pharmacy	10/31/2023	CA Board of Pharmacy, CI 2022-99327	Citation and Fine
PHY 51636	Kaiser Permanente Pharmacy #105	1/11/2024	CA Board of Pharmacy, CI 2022-99447	Citation and Fine
PHY 37509	Kaiser Health Plan MOB 1 PHY 684	3/7/2024	CA Board of Pharmacy, CI 2021-96238	Citation and Fine
PHY 46807	Kaiser Permanente Pharmacy #608	3/7/2024	CA Board of Pharmacy, CI 2022-99095	Citation and Fine
PHY 51974	Kaiser Permanente Pharmacy #260	3/22/2024	CA Board of Pharmacy, CI 2022-99498	Citation and Fine Upheld
PHY 58091	Kaiser Permanente Pharmacy #910	5/3/2024	CA Board of Pharmacy, CI 2023-101599	Citation and Fine
PHY 42151	Kaiser Foundation CPP Pharmacy 251	5/15/2024	CA Board of Pharmacy, CI 2022-99903	Letter of Admonishment
PHY 30676	Kaiser Health Plan Cypress MOB PHY 371	6/28/2024	CA Board of Pharmacy, CI 2022-100584	Citation & Fine with Order of Abatement
PHY 41612	Kaiser Permanente Pharmacy #985	9/10/2024	CA Board of Pharmacy, CI 2022-99537	Citation
PHY 41612	Kaiser Permanente Pharmacy #985	8/19/2025	DEA Los Angeles Field Division	Letter of Admonishment
PHY 35902	Kaiser Permanente Pharmacy #603	8/21/2025	CA Board of Pharmacy, CI 2022-100794	Citation and Fine
PHY 41612	Kaiser Permanente Pharmacy #985	4/10/2026	CA Board of Pharmacy, CI 2024-106309	Citation and Fine
PH04283	Renown Pharmacy	4/15/2026	Nevada Board of Pharmacy, 25-139-PH-N	Stipulation and Order
PHY 42151	Kaiser Foundation CPP Pharmacy 251	5/8/2026	CA Board of Pharmacy, CI 2024-10894	Citation and Fine
PHY 41738	Kaiser Health Plan Oakhurst PHY 801	7/31/2026	CA Board of Pharmacy, CI 2025 112414	Citation

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Kaiser Permanente Fifth Street Pharmacy

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 803 West 5th Street

City: Reno State: NV Zip: 89503

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 775-678-4101 Website: www.kp.org

Licensing Company Email: co-pharmacy.compliance@kp.org

Section 2: Personal Information

First: Christine Middle: Jenny Last: Lo

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Livermore State: CA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Skyline High School			08/00 - 06/04
Address	**City**	**State**	**Zip**
12250 Skyline Boulevard	Oakland	CA	94619
Diploma/Degree obtained, if any			
High School Diploma			

School Name			From - To (MM/YY – MM/YY)
University of California, David			08/04 - 06/09
Address	**City**	**State**	**Zip**
One Shields Avenue	Davis	CA	95616
Diploma/Degree obtained, if any			
Bachelor of Arts			

School Name			From - To (MM/YY – MM/YY)
Roosevelt University (College of Pharmacy)			06/13 - 5/16
Address	**City**	**State**	**Zip**
1400 N Roosevelt Blvd	Schaumburg	IL	60173
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]	City	State	[redacted]
05/25 - Current		Livermore	CA	
From - To (MM/YY – MM/YY)	[redacted]	City	State	[redacted]
01/97 - Current		Oakland	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Kaiser Permanente			06/21 - Current
Business Address	**City**	**State**	**Zip**
300 Pullman St. Building G, 1st Floor	Livermore	CA	94551
Phone	**Title**		**Number of Employed Hours**
925-960-6966	Supv, Pharmacy Care Delivery, Home Delivery Services		40 hrs/wk
Description of Duties			
Provide leadership, supervision and direction to subordinate pharmacy supervisors, lead pharmacists, pharmacists, techs, and clerks. Ensure compliance with Federal and State laws, regulations, policies and perform other duties as required.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8/14/26
Date

I, Christine Lo, **certify that as the designated representative for**

Kaiser Permanente Fifth Street Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CL I am at least 21 years of age;
3. CL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christine Lo

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/14/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christine Lo

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/14/26

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Alameda

I, CHRISTINE LO, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/14/26

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

SEE NOTARY ATTACHMENT
NOTARY INITIALS: SH
DATE: August 14, 2026

(Seal)

CALIFORNIA JURAT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California)

County of Alameda)

Subscribed and sworn to (or affirmed) before me on this 14th day of August, 20 26, by Christine Lo,

proved to me on the basis of satisfactory evidence to be the person~~(s)~~ who appeared before me.

SHUSHAN AGADJANIAN
COMM. #2523550
Notary Public - California
Alameda County
My Comm. Expires July 16, 2029

(Seal)

Signature Shushan Agadjanian

Optional Information

Although the information in this section is not required by law, it could prevent fraudulent removal and reattachment of this jurat to an unauthorized document and may prove useful to persons relying on the attached document.

Description of Attached Document

This certificate is attached to a document titled/for the purpose of

NV State Board of Pharmacy. Designated Representative Application.

containing 9 pages, and dated August 14, 2026.

Additional Information

Method of Affiant Identification

Proved to me on the basis of satisfactory evidence:
○ form(s) of identification ○ credible witness(es)

Notarial event is detailed in notary journal on:
Page # _____ Entry # _____

Notary contact: _____

Other

☐ Affiant(s) Thumbprint(s) ☐ Describe: _____

© Copyright 2007-2018 Notary Rotary, PO Box 41400, Des Moines, IA 50311-0507. All Rights Reserved. Item Number 101884. Please contact your Authorized Reseller to purchase copies of this form.

License #	License Name
PHY 46384	Kaiser Permanente Pharmacy #833
PHY 37029	Kaiser Permanente Pharmacy #113
PHY 49886	Kaiser Permanente Pharmacy #249
PHY 43518	Kaiser Health Plan Manteca PHY 491
PHY 43518	Kaiser Health Plan Manteca PHY 491
PHY 46987	Kaiser Permanente Pharmacy #431
PHY 47092	Kaiser Permanente Pharmacy #215
PHY 51709	Kaiser Permanente Pharmacy #607
PHY 41612	Kaiser Permanente Pharmacy #985
PHY 50985	Kaiser Permanente Pharmacy #610
PHY 41612	Kaiser Permanente Pharmacy #985
PHY 43294	Kaiser Health Plan MOB PHY 401
PHY 41612	Kaiser Permanente Pharmacy #985
PHY 37446	Kaiser Health Plan 1 New PHY 601
PHY 37047	Kaiser Health Plan MOB 1 PHY 211
PHY 43605	Kaiser Health Plan Two North PHY 637
PHY 51636	Kaiser Permanente Pharmacy #105
PHY 51530	Kaiser Permanente Pharmacy #264
LSC 100395	Kaiser Permanente Pharmacy #377 (permanently closed)
PHY 37411	Kaiser Health Plan C PHY 723
PHY 37410	Kaiser Health Plan B PHY 722
PHY 40642	Kaiser Health Plan MOB 1 PHY 511
PHY 36679	Kaiser Health Plan South 1 PHY 471
PHY 56090	Kaiser Permanente Pharmacy #971

PHY 30218	Kaiser Permanente Pharmacy #014
PHY 42151	Kaiser Foundation CPP Pharmacy 251
PHY 50836	Kaiser Permanente Pharmacy #596
PHY 49285	Kaiser Permanente Pharmacy #266
PHY 40642	Kaiser Health Plan MOB 1 PHY 511
PHY 37509	Kaiser Health Plan MOB 1 PHY 684
PHY 30676	Kaiser Health Plan Cypress MOB PHY 371
PHY 37446	Kaiser Health Plan 1 New PHY 601
PHY 35902	Kaiser Permanente Pharmacy #603
PHY 39805	Kaiser Permanente Pharmacy #197
PHY 46807	Kaiser Permanente Pharmacy #608
PHY 43312	Kaiser Permanente Pharmacy
PHY 51636	Kaiser Permanente Pharmacy #105
PHY 51974	Kaiser Permanente Pharmacy #260
PHY 41612	Kaiser Permanente Pharmacy #985
PHY 42151	Kaiser Foundation CPP Pharmacy 251
PHY 58091	Kaiser Permanente Pharmacy #910
PHY 41612	Kaiser Permanente Pharmacy #985
PHY 42151	Kaiser Foundation CPP Pharmacy 251
PHY 41612	Kaiser Permanente Pharmacy #985
PH04283	Renown Pharmacy
PHY 41612	Kaiser Permanente Pharmacy #985

Date	Agency / Case
11/28/2016	CA Board of Pharmacy, AC201500553300
11/1/2017	CA Board of Pharmacy, AC201500580600
9/10/2019	CA Board of Pharmacy, AC201700631700
4/19/2013	CA Board of Pharmacy, CI 2010-48794
5/2/2013	CA Board of Pharmacy, CI 2011-51585
7/8/2013	CA Board of Pharmacy, CI 2011-51929
2/26/2018	CA Board of Pharmacy, CI 2015-66539
3/29/2016	CA Board of Pharmacy, CI 2015-69670
2015	CA Board of Pharmacy, CI 2015-69738
5/20/2016	CA Board of Pharmacy, CI 2015-70429
4/30/2018	CA Board of Pharmacy, CI 2016-74300
1/23/2018	CA Board of Pharmacy, CI 2016-74415
5/15/2018	CA Board of Pharmacy, CI 2016-74548
3/2/2018	CA Board of Pharmacy, CI 2017-76653
11/17/2017	CA Board of Pharmacy, CI 2017-77550
10/17/2019	CA Board of Pharmacy, CI 2018-81807
12/12/2019	CA Board of Pharmacy, CI 2018-82283
10/15/2020	CA Board of Pharmacy, CI 2018-84390
1/11/2021	CA Board of Pharmacy, CI 2019-86808
5/5/2020	CA Board of Pharmacy, CI 2019-87818
5/5/2020	CA Board of Pharmacy, CI 2019-87820
5/5/2021	CA Board of Pharmacy, CI 2019-88682
12/15/2021	CA Board of Pharmacy, CI 2020-92090
6/22/2022	CA Board of Pharmacy, CI 2021-93681

9/16/2022	CA Board of Pharmacy, CI 2021-94164
12/28/2022	CA Board of Pharmacy, CI 2021-94830
2/28/2023	CA Board of Pharmacy, CI 2021-95125
8/8/2023	CA Board of Pharmacy, CI 2021-95658
11/18/2022	CA Board of Pharmacy, CI 2021-95786
3/7/2024	CA Board of Pharmacy, CI 2021-96238
6/28/2024	CA Board of Pharmacy, CI 2022-100584
10/6/2023	CA Board of Pharmacy, CI 2022-100594
8/21/2025	CA Board of Pharmacy, CI 2022-100794
7/14/2023	CA Board of Pharmacy, CI 2022-97475
3/7/2024	CA Board of Pharmacy, CI 2022-99095
10/31/2023	CA Board of Pharmacy, CI 2022-99327
1/11/2024	CA Board of Pharmacy, CI 2022-99447
3/22/2024	CA Board of Pharmacy, CI 2022-99498
9/10/2024	CA Board of Pharmacy, CI 2022-99537
5/15/2024	CA Board of Pharmacy, CI 2022-99903
5/3/2024	CA Board of Pharmacy, CI 2023-101599
4/10/2026	CA Board of Pharmacy, CI 2024-106309
5/8/2026	CA Board of Pharmacy, CI 2024-10894
9/24/2021	CA Division of Occupational Safety & Health, 950635
4/15/2026	Nevada Board of Pharmacy, 25-139-PH-N
8/19/2025	DEA Los Angeles Field Division

Action	PDF
Revocation Stayed (Probation Completed 01-May-2020)	Yes
Revocation Stayed (Probation Completed 31-Oct-2020)	Yes
Stipulated Settlement and Disciplinary Order	Yes
Citation	Yes
Letter of Admonishment	Yes
Citation and Fine	Yes
Letter of Admonishment Upheld	Yes
Citation	Yes
Citation and Fine	Yes
Citation and Fine	Yes
Citation and Fine	Yes
Citation and Fine	Yes
Citation	Yes
Citation	Yes
Letter of Admonishment	Yes
Citation	Yes
Citation & Fine with Order of Abatement	Yes
Citation	Yes
Citation & Fine with Order of Abatement	Yes
Citation	Yes
Citation	Yes
Letter of Admonishment	Yes
Letter of Admonishment	Yes
Letter of Admonishment	Yes

Citation	Yes
Citation and Fine	Yes
Citation and Fine	Yes
Citation and Fine	Yes
Citation and Fine	Yes
Citation and Fine	Yes
Citation & Fine with Order of Abatement	Yes
Citation and Fine	Yes
Citation and Fine	Yes
Citation and Fine	Yes
Citation and Fine	Yes
Citation and Fine	Yes
Citation and Fine	Yes
Citation and Fine Upheld	Yes
Citation	Yes
Letter of Admonishment	Yes
Citation and Fine	Yes
Citation and Fine	Yes
Citation and Fine	Yes
Citation and Notification of Penalty	Yes
Stipulation and Order	Yes
Letter of Admonishment	Yes

4LL

2016

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	■ Service Modification*	☐ Nuclear	DEA #: _____
	■ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	■ Non-sterile Compounding
			■ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH PH03010		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Medicap Compounding Center - Coralville

Physical Address: 1900 James St #10-B

City: Coralville State: IA Zip: 52241

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 319.354.6006 Toll Free # (NAC 639.708, NRS 639.23286): 1-877-268-2272

Fax: 319.354.6050 Contact Email: contracting.50state@onerorx.com

Website: www.nucara.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Christopher Petersen

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24070

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Christopher Petersen	NV Pharmacist Registration #: 24070
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NR5.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Iowa

Parent Company (if any): Local Health Iowa, Inc.

Corporation/Organization Name: GRX Holdings, LLC

Mailing Address: 2929 Westown Parkway Suite 100

City: West Des Moines State: IA Zip: 50266

Telephone: 515-440-1270 Email: mike.fuller@onerorx.com

Contact Person Name: Michael Fuller

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Medicap Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Michael Fuller

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

6/23/2020

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Fuller, President

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

Date 6/23/2026

Board Use Only	Date Received: 7/7/26	Amount: $500-CK 1000002870 ✓

CONFIDENTIAL/EXEMPT FROM
FREEDOM OF INFORMATION ACT AND
SIMILAR STATE REQUESTS

Ownership Information

Ownership & Leadership of Applicant Entity - NV License # PH03010

Applicant: **Medicap Compounding Center - Coralville**
1900 James Sr #10-B, Coralville, IA 52241

Ownership: The Applicant entity is wholly owned (100%) by GRX Holdings, LLC
GRX Holdings, LLC is wholly owned (100%) by Local Health Iowa, Inc.

Officers of GRX Holdings, LLC
Joseph Dunham - CEO
Michael Fuller - President
Steven Donnelly - Vice President
Chris Mahlstadt - Secretary
Austin Tolander - Treasurer

Ownership & Leadership of Local Health Iowa, Inc.

Ownership: Local Health Iowa, Inc. is wholly owned (100%) by OneroRx, Inc.

Officers of Local Health Iowa, Inc.
Joseph Dunham - CEO/President
Chris Mahlstadt - Secretary
Austin Tolander - CFO/Treasurer

Leadership of OneroRx, Inc.

Officers of OneroRx, Inc.
Joseph Dunham - CEO
Amy Mitchell - President
Chris Mahlstadt - Secretary
Austin Tolander - CFO/Treasurer

Please see the attached pre- and post-closing Corporate Organization chart for reference.

2022

IOWA SECRETARY OF STATE
PAUL D. PATE

CERTIFICATE OF EXISTENCE

Issue Date: 5/2/2025

Name: GRX HOLDINGS, LLC (489DLC - 361302)
Date of Formation: 4/2/2008
Duration: PERPETUAL

I, Paul D. Pate, Secretary of State of the State of Iowa, custodian of the records of incorporations, certify the following for the limited liability company named on this certificate:

a. The entity is in existence and duly formed under the laws of Iowa. A certificate of organization has been filed and has taken effect.

b. All fees, taxes and penalties required under the Revised Uniform Limited Liability Company Act and other laws due the Secretary of State have been paid.

c. The most recent biennial report required has been filed with the Secretary of State.

d. The Secretary of State has not administratively dissolved the limited liability company.

e. The Secretary of State has not filed either a statement of dissolution or statement of termination. The records of the Secretary of State do not otherwise reflect that the limited liability company has been dissolved or terminated.

f. A proceeding is not pending under section 489.705

Certificate ID: **CS304109**

To validate certificates visit:
sos.iowa.gov/ValidateCertificate

Paul D. Pate, Iowa Secretary of State

2023

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Medicap Pharmacy

Pharmacy/Wholesaler License # (if applicable): PH03010

Physical Address: 1900 James St #10-B

City: Coralville State: IA Zip: 52241

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 319.354.6006 Website: www.nucara.com

Licensing Company Email: coralville@nucara.com

Section 2: Personal Information

First: Christopher Middle: Last: Petersen

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Coralville State: IA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)		
U of Iowa College of Pharmacy	08/14 - 05/18		
Address	**City**	**State**	**Zip**
180 S. Grand Ave, Iowa City, IA	Iowa City	IA	52242
Diploma/Degree obtained, if any			
PharmD			

School Name	From - To (MM/YY – MM/YY)		
U of Iowa	08/11 - 05/14		
Address	**City**	**State**	**Zip**
	Iowa City	IA	52242
Diploma/Degree obtained, if any			
N/A			

School Name	From - To (MM/YY – MM/YY)		
Xavier High School	08/07 05/11		
Address	**City**	**State**	**Zip**
6300 42nd St NE	Cedar Rapids	IA	52411
Diploma/Degree obtained, if any			

School Name	From - To (MM/YY – MM/YY)		
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name	From - To (MM/YY – MM/YY		
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/20 - Present	[redacted]	Tiffin	IA	[redacted]
08/19 - 06/20		Coralville	IA	
08/17 - 08/19		North Liberty	IA	
08/16 - 08/17		Iowa City	IA	
08/15 - 08/16		Iowa City	IA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Nucara Pharmacy			05/18 - 03/26
Business Address	**City**	**State**	**Zip**
1900 James St. STE 10	Coralville	IA	52241
Phone	**Title**	**Number of Employed Hours**	
319-354-6006	RPh / PIC	40 hrs / week x 8 yrs	
Description of Duties			
PIC			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Christopher Petersen, certify that as the designated representative for

Medicap Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CP I am at least 21 years of age;
3. CP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christopher Petersen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4-7-26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Petersen

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) — Date: 4-8-26

Please have this section completed in the presence of a Notary Public.

State of Iowa, ss. County of Johnson

I, Mr. [signature], being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature — **Date:** 4-8-26

Subscribed and Sworn to before me this 8th day of April 2026

Martha A. Donar

Notary Public Signature

MARTHA A. DONAR
Commission Number 870427
My Commission Expires
January 29, 2029

(Seal)

DEMOGRAPHICS

License # :
1647

Business Name :
NuCara Pharmacy #1

Inspection Date
04/22/2025

Address
1900 James St

Zip :
52241

City
Coralville

State
IA

Phone :
(319) 354-6006

Fax
(319) 354-6050

Business Email :
license@nucara.com

PIC
Christopher David Petersen

PIC Email :

PIC License #
23334

PIC License Exp Date :
06/30/2026

DEA #

CSA Number
1108592

CSA Expiration Date :
10/31/2025

Shipping Compounds Out of Iowa
NO

Compliant with NABP Reporting
YES

Averages

Average Prescription volume per week
321

Most Recent Annual CS Inventory Date
10/09/2024

Number of Pharmacist Hours per week
56

Number of Technician Hours per week
200

Number of Intern Hours per week
20

Number of PSP Hours per week
0

Pharmacy Practice/Services

General Dispensing
YES

Central Rx Processing
NO

Hospital
NO

Mail Order Only
NO

Central Rx Filling
NO

Home Infusion
NO

Nuclear
NO

Care Facility Filling
NO

Care Facility Consulting
NO

Emergency Drug Kits
NO

Unit Dose
NO

Home Health/DME
NO

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Medicap Compounding Center - Coralville

NV Pharmacy or Outsourcing facility license # (if applicable): PH03010

Physical Address: 1900 James St. STE 10-B

City: Coralville State: IA Zip: 52241

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 319-354-6006 Toll Free # (NAC 639.708, NRS 639.23286): 1-877-268-2272

Fax: 319-354-6050 Contact Email: 8502@onerorx.com

Website: www.nucara.com

Nevada Business License # (if applicable)

Supervising/Managing Pharmacist Name (NRS 639.220): Christopher Petersen

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24070

Name of Designated Person(s) as defined by revised USP-797 guidelines: Christopher Petersen Miranda Verry Shelby Stender

Email of Designated Person(s): chris.petersen@onerorx.com mirandalv88@gmail.com thisismyworkemailsilly@gmail.com

Telephone of Designated Person(s): 319-354-6006

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ☐ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☐ Yes ■ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ■ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 2/26/26

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Monthly

10. Will you be performing sterile hazardous drug compounding? Yes ■ No

If you marked "Yes", you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

12. What laboratory performs your sterility or endotoxin testing?

Name: Pharmetric Laboratory

Address: 7265 Ulmerton Rd

City: Largo State: FL Zip: 33771

Telephone: 727-209-5778

13. What is your procedure for visual inspection of compounded sterile products?

In-process visual inspections are completed by capturing a photo of the volume of the ingredients measured in syringes. Visual inspections are also completed by the pharmacist during post-check with a IV inspection box with a black UV or white LED light to determine the absence or inclusion of particulates.
Final visual inspections are completed prior to dispensing the final product to patients to verify the absence of particulates that may have formed during storage.

14. How often do you perform glove fingertip and medial fill testing?

Every 6 months for compounding technicians.
Every year for pharmacists with direct oversight of compounding technicians.

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Initial: didactic training consisting of 20 hours of CE through trchealthcare's Critical Point's Sterile Compounding Training program, reading USP 797 and USP 800, observation and feedback provided by a competent and sterile trained technician, passed gloved fingertip and thumb testing (3 times), passed media fill with gloved fingertip test and surface sample. Passed sample potency and sterility tests processed by Pharmetric Laboratory. Training on sterile equipment. Passed sterile competency quiz.
Ongoing: annual didactic training through Critical Point's Sterile Training program, annually reading USP 797 and USP 800, observation and feedback provided by a competent and sterile trained technician, passed media fill with gloved fingertip test and surface sample (every 6 months). Passed sample potency and sterility tests processed by Pharmetric Laboratory (annually). Training on sterile equipment. Passed sterile competency quiz.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Contec PeridoxRTU (Sterile) - disinfectant, cleaner, sporicidal, deactivation (hazardous), decontamination (hazardous)
Hazardous: daily, weekly, monthly, periodic (applied twice for decontamination and disinfection); Non-Hazardous: Monthly (as sporicidal)
Contec TB1-3300 (Sterile) - disinfectant, cleaner
Hazardous: N/A; Non-Hazardous: daily, weekly
Contec Sterile 70% Isopropanol (IPA) - disinfectant
Hazardous: Following Peridox use; Non-Hazardous: daily, weekly, monthly, periodic
Prosat Sterile Presaturated Wipe - disinfectant
Hazardous: Following Peridox use; Non-Hazardous: daily, weekly, monthly, periodic

Daily Clean: Work surfaces, high-touch areas, floors, PEC interior and items inside: Periodox, sterile IPA
Monthly Clean: All daily clean activities, ceilings, walls, doors, PEC exterior, all surfaces and chairs (including wheels and underside of surfaces), supply bins, and trash receptacles.

17. Who performs the sterile compounding process at your facility?

Certified pharmacy technicians trained for sterile compounding.

18. Who is responsible and accountable for the sterile compounding process at your facility?

Certified pharmacy technicians and pharmacists trained for sterile compounding.

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

We use an algorithm by KodiaKooler who conducted 3rd party testing on medication storage and external ambient temperature. If a product is stored frozen, we ship on dry ice in an insulated shipping kit using UPS ground shipping. We have data showing UPS is able to deliver anywhere in Iowa within 24 hours. We don't ship sterile products out-of-state.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? Make: NUAIRE; Model: NU-301-430, Make: NUAIRE; Model: NU-540-400 Make: NUAIRE; Model: NU-201-330		
2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	■ No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

The following statements are written on the frequently asked questions page of patient advisory leaflets (PAL):
-Refer to your individual state's regulations for drug disposal. Many local law enforcement agencies participate in "take-back" days several times per year. These local events and other local permanent collection programs can be found on the DEA website.
-Written instructions concerning the safe disposal of unused drugs are provided upon patient request.

If applicable:
- It is important to keep this product out of direct contact with pregnant or nursing mothers. (Statement on PAL)
- Do not use if pregnant or breastfeeding. (Auxiliary label)
- Wash your hands before and after taking this medication. (Statement on PAL)
- Wash hands before and after use. (Auxiliary label)
- Wear gloves while handling this medication. (Statement on PAL)
- Wear gloves (Auxiliary label)

- A letter is sent inside the package for products shipped on dry ice titled Patient Disposal and Proper Handling of Dry Ice. "Dry ice is not for consumption. Do not touch dry ice. Do not flush or place dry ice in sink or down a drain. Do not throw dry ice into garbage. Do not attempt to preserve dry ice.
1. Retrieve product/medication and any accompanying paperwork from the insulated shipping kit.
2. Leave open ends of the insulated shipping kit up with Styrofoam lid removed.
3. Place in a low-frequented location, out of reach of children or animals to allow dry ice to sublimate (to pass from solid to vapor-state)
4. After dry ice has finished sublimation dispose of container in garbage.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Didactic training consisting of 20 hours of CE through trchealthcare's Critical Point's Sterile Compounding Training program, reading USP 797 and USP 800, observation and feedback provided by a competent and sterile trained technician, passed gloved fingertip and thumb testing (3 times), passed media fill with gloved fingertip test and surface sample. Passed sample potency and sterility tests processed by Pharmetric Laboratory. Training on sterile equipment. Passed sterile competency quiz.

Didactic training: Hazardous drug overview, containment primary and secondary engineering controls, personal protective equipment for hazardous drug handling, hazardous drug work practice: receiving through transport to patients, and decontamination and spill management.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?

5. What is the frequency for completing surface sampling?		
6. What is the frequency for using sporicidal agents?		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Petersen

Name of Person who Completed the Form

PIC

Title



Signature (copies or stamps not accepted)

6/17/26

Date

Board Use Only	Date Received: 7/7/26 Date Approved: _____ Approved By: _____

DEMOGRAPHICS

License # :	Business Name :	Inspection Date :
1647	NuCara Pharmacy #1	04/22/2025

Address :

1900 James St

Zip :	City :	State :
52241	Coralville	IA
Phone :	Fax :	Business Email :
(319) 354-6006	(319) 354-6050	license@nucara.com
PIC :	PIC Email :	PIC License # :
Christopher David Petersen		23334
PIC License Exp Date :	DEA # :	CSA Number :
06/30/2026		1108592
CSA Expiration Date :	Shipping Compounds Out of Iowa	Compliant with NABP Reporting
10/31/2025	NO	YES

Averages

Average Prescription volume per week	Most Recent Annual CS Inventory Date	Number of Pharmacist Hours per week
321	10/09/2024	56
Number of Technician Hours per week	Number of Intern Hours per week	Number of PSP Hours per week
200	20	0

Pharmacy Practice/Services

General Dispensing	Central Rx Processing	Hospital
YES	NO	NO
Mail Order Only	Central Rx Filling	Home Infusion
NO	NO	NO
Nuclear	Care Facility Filling	Care Facility Consulting
NO	NO	NO
Emergency Drug Kits	Unit Dose	Home Health/DME
NO	NO	NO

OTC Pseudoephedrine Sales

NO

Exempt CV Dispensing

NO

Prepackaging

NO

EMS

NO

Collaborative Practice Agreements

NO

Technician Product Verification

NO

Prescription Delivery/Mail-outs/Mail Order

YES

Medication Therapy Management

NO

Statewide Protocol-Naloxone

NO

Statewide Protocol-Immunization

NO

Statewide Protocol-Nicotine Replacement

YES

Statewide Protocol-Strep A Test and Treat

NO

Statewide Protocol-Influenza Test and Treat

NO

CLIA-Waived Testing

NO

Compliance Packaging/MedPaks

NO

Naloxone Standing Order

NO

Human Patients

YES

Veterinary – Companion Animals

YES

Veterinary – Food-producing Animals

NO

DEA-registered Controlled Substances Collector

NO

Non-Controlled Substance Collector Only

NO

COVID-19 Diagnostic

NO

COVID-19 Antibody

NO

Statewide Protocol-COVID-19 Test and Treat

NO

Syringes sold without a prescription

YES

Other

NO

Collaborative Practice Explanation

Other (if Other please explain)

Compounding

Sterile High-Risk

YES

Sterile Medium-Risk

YES

Sterile Low-Risk

YES

Sterile Immediate Use	Sterile Hazardous Drugs	Sterile Anticipatory
NO	YES	NO
Sterile Shipping out-of-state	% of sterile compounded preparations shipped out of state during the previous year	Sterile Number of Facilities
NO	0	1
		Sterile for patients in other facilities
		NO
Non Sterile Simple	Non Sterile Moderate	Non Sterile Complex
YES	YES	YES
Non Sterile Anticipatory	Non Sterile Hazardous Drugs	Prescriber Office Use
YES	YES	NO
Number of sterile compounded preparations dispensed into Iowa last year	Number of non-sterile compounded preparations dispensed into Iowa last year	Pursuant to Patient-Specific Rx
496	2933	YES

Accreditations

VIPPS	PCAB	ACHC	JCAHO
NO	YES	YES	NO
DMEPOS	VPP	None	
NO	NO	NO	

Other (if Other please explain)

Community Focused

C = Compliant, R = Reminder, D = Deficiency, NA = Not Applicable, NR = Not Reviewed

1	Review of pharmacy environment, inventory control and security measures (basic alarm system and video surveillance system w/retention via P&Ps)	◉C ○D ○NA ○NR ○R 657-6.3, 6.7, 8.5, 8.7, 10.13
2	Review of staff functions, activities, and patient counseling practices	◉C ○D ○NA ○NR ○R 657-3.21, 3.22, 3.23, 3.24, 4.6, 5.17, 5.18, 5.22, 6.14
3	Review of patient information and processes to ensure complete prospective drug utilization review (including auto refill review/update)	◉C ○D ○NA ○NR ○R 657-6.13, 8.21

4	Review of PMP registration and utilization; submission of naloxone/CV dispensing; PMP review prior to CV OTC sale; CV sales authorized only by RPh or Intern; CV sales record contains: 1) Purchaser name/address 2) Name/qty of CV purchased 3) Purchase date 4) RPh/Intern name or ID	◉C ○D ○NA ○NR ○R	657-10.33; 657-37.3(2)
5	Review of Continuous Quality Improvement program and utilization	◉C ○D ○NA ○NR ○R	657-8.26
6	Review of CIII-V accountability measure [options: perpetual inventory, documented audit/reconciliation every 6 months, documented cycle counts covering all CSs every 90 days, other board-approved measure] Documented audit on a quarterly basis - reviewed	◉C ○D ○NA ○NR ○R	657-10.20
7	Registrant stock is disposed of via IA-licensed distributor or in authorized manner; Registrant does not accept CSs back for disposal unless authorized collector	◉C ○D ○NA ○NR ○R	657-10.22(1), 10.23

NOTES

Deficiencies

Reminders

- Annual CS inventory taken within 372 days of previous inventory and includes: 1) All CSs (will-call, PSE, EMS, e-kit, outdated stocks) 2) Collection receptacle liner information, if applicable (657-10.19(1))
  CS audit form should be sufficient as the annual CS inventory if dosage form/strength as applicable (most all APIs) and open/close of business is identified on the form and must include expired CSs as well.

AFFIRMATION

Representative Email :

cpetersen@nucara.com

Note : I (The "Facility Representative" signing below) acknowledge and affirm that the areas of noncompliance identified (if any) in this inspection report will be remedied within 30 calendar days. I further acknowledge and understand that a complaint may be initiated due to any areas of noncompliance identified in this inspection report and the Board may determine that disciplinary action against my license and the facility's license or registration is warranted.

Board of Pharmacy Inspector :

Britney Origer



Facility Representative

Christopher David Petersen



Iowa Board of Pharmacy Disclaimer : During this inspection, not all rules and regulations may have been inspected for compliance. This does not preclude or excuse your compliance with all applicable rules and regulations of the Iowa Board of
Pharmacy

Compounding - Nonsterile / Sterile / HD

1647 / Nucara Pharmacy #1 / 22 Apr 2025 / Britney Origer

Complete

Flagged items	7	**Actions**	0

Site conducted	Unanswered
Conducted on	22.04.2025 13:41 CDT

Sterile Compounding Inspection Report

License number	1647
Facility name	Nucara Pharmacy #1
Location	1900 James St., Coralville, IA 52241
Prepared by	Britney Origer

in the presence of PIC Chris Petersen

Flagged items

7 flagged

Inspection / Garbing / hand hygiene

Gloved fingertip/thumb sampling is compliant, unless identified below (797-2.2). Identify any element missing or not compliant:

Samples are incubated (inverted) at 30-35C (86-95F) for min. 48 hrs then 20-25C (68-77F) for min. 5 days

CFU counts must be documented per hand

Currently each GFT is done with both bacteria (paddles) and fungal (plates) media for each hand but only one sample is documented with total CFU results, not individual. Samples are also not being incubated at correct temperature per the USP 797 revisions. Plates incubated at 26-30 degrees C for 7 days and paddles incubated at 30-35 degrees C for 72 hours

Inspection / Garbing / hand hygiene

Result of evaluations and corrective actions, if failed (from visual observation or GFT sampling), are documented and documentation is compliant, unless identified below (797-2.2). Identify any element of documentation missing:

For incubation, the starting temperatures for each interval, the dates of incubation, and the results

Results of GFT samples not individually documented; No incubation dates/temps for each interval

Inspection / Media-Fill Testing (MFT)

MFT is compliant, unless identified below (797-2.3). Identify any noncompliance:

At completion of MFT, containers are incubated at 20-25C (68-77F) for 7 days then 30-35C (86-95F) for 7 days

MFT are currently being incubated at 25-35 degrees C for 14 days instead of the two required intervals

Inspection / Media-Fill Testing (MFT)

Results of evaluations and corrective actions, if failed (visible turbidity/visual manifestations of growth within 14 days), are documented and documentation is compliant, unless identified below (797-2.3). Identify element missing:

For incubation, the starting temperatures for each interval, dates of incubation, and results

Inspection / Facility / Equipment / Category 1 or 2 in Cleanroom Suite

The cleanroom suite is compliant, unless identified below (797-4). Identify any noncompliance:

All surfaces in the classified areas are smooth, impervious, free from cracks and crevices, and non-shedding (797-4.3)

Observed what appears to be rust on carts in the sterile buffer room and anteroom which is considered an insanitary condition

Inspection / Facility / Equipment / Certification / recertification

The licensee is compliant in its surface sampling procedures for viable particles, unless identified below (797-6.3). Identify any areas not compliant:

Samples must be inverted, incubated at 30-35°C at least 48 hrs, reviewed for CFU, incubated at 20-25°C at least 5 days, reviewed for CFU (or follow the alternative procedure identified in Box 6-1)

Bacterial and fungal media samples used for SS; Fungal media being incubated at 26-30 C for 7 days instead of 20-25 C. Bacterial media compliant at 30-35 C x 72 hours

Inspection / Records / Labeling / BUDs / Master Formulation Records

Licensee maintains compliant Master Formulation Records for all CSPs compounded for more than 1 patient or for CPSs prepared from nonsterile components, unless identified below (797-11.1). Identify any aspect of the MFR missing:

Type and size of container-closure system(s)

Reviewed phentolamine, papaverine, alprostadil injection (Trimix) MFR - packaging and directions are for a 10 ml vial for multidose use but current process is to fill 5 - 1ml vials per batch to align with USP 797 revision changes.

Inspection

7 flagged

Does this licensee engage in non-sterile compounding activities?	N/A
See other report	
Does this licensee engage in sterile compounding activities?	Yes
The licensee has a designated individual responsible for oversight of compounding activities (797-1.1).	Compliant
Immediate Use / Preparation per approved labeling	
Does the licensee engage in preparation of CSPs for immediate use?	No
Preparation of conventionally manufactured sterile products and docking/activation of proprietary bag/vial systems is compliant, unless identified below (797-1.4). Identify any element that is not compliant (and requires full compliance with USP 797 for Category 1 or Category 2):	Not reviewed
Not used here	
Standard Operating Procedures (SOPs)	
The licensee has compliant SOPs, unless identified below (797). Identify any SOPs missing:	SOPs are compliant
If the licensee engages in compounding of HDs, SOPs are complete, documented, and reviewed at least every 12 months, unless identified below (800). [If no compounding or already reviewed in NS compounding, select N/A] Identify any SOPs that are missing:	Licensee does not engage in HD compounding or HD SOPs have previously been reviewed
Reviewed in the nonsterile inspection report	
HDs	
The licensee engages in sterile compounding of hazardous drugs (if review of HD compounding already complete under non-sterile compounding, may skip).	N/A
See nonsterile HD report	
Training Program	
The licensee has a designated person to oversee personnel training (797-2).	Compliant
The licensee has a written training program which describes the required training, frequency of training, and process for evaluation of performance of individuals (797-2).	Compliant

Training is documented, completed before compounding of CSPs, and repeated every 12 months, unless identified below (797-2.1, 797-19). Identify any element of required training which is missing:

Training program is complete and documented

All compounding personnel have completed written or electronic testing every 12 months (797-2.1).

Compliant

All personnel handling CSPs or entering the compounding area have completed training/demonstrated competency in maintaining the quality of the environment in which they are performing their assigned task (797-2.1).

Compliant

If the licensee has only one person in the compounding operation, the individual has documented that they have obtained training and demonstrated competency (797-2.1).

N/A

Personnel responsible for cleaning/disinfecting are trained when there are changes in cleaning/disinfecting procedures (797-7)

N/A

No recent changes

If the facility compounds with HDs, training is documented, complete and repeated every 12 months, unless identified below (800-9) Identify any elements that are missing:

Not reviewed

previously reviewed with nonsterile HD

Garbing / hand hygiene

2 flagged

All compounding personnel have documented competency for proper hand hygiene and garbing procedures (via visual observation) initially and every 6 months (797-2.2).

Compliant

All compounding personnel have documented competency before compounding CPSs by successful completion of three separate gloved fingertip/thumb samples for both hands (zero CFUs) and every 6 months following media-fill testing (no more than 3 CFU total from both hands) (797-2.2).

Compliant

Gloved fingertip/thumb sampling is compliant, unless identified below (797-2.2). Identify any element missing or not compliant:

Samples are incubated (inverted) at 30-35C (86-95F) for min. 48 hrs then 20-25C (68-77F) for min. 5 days

CFU counts must be documented per hand

Currently each GFT is done with both bacteria (paddles) and fungal (plates) media for each hand but only one sample is documented with total CFU results, not individual. Samples are also not being incubated at correct temperature per the USP 797 revisions. Plates incubated at 26-30 degrees C for 7 days and paddles incubated at 30-35 degrees C for 72 hours

Result of evaluations and corrective actions, if failed (from

For incubation, the starting temperatures for each interval,

visual observation or GFT sampling), are documented and documentation is compliant, unless identified below (797-2.2). Identify any element of documentation missing:

the dates of incubation, and the results

Results of GFT samples not individually documented; No incubation dates/temps for each interval

Individuals at higher risk of contaminating CSPs/compounding environment report conditions (such as rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infection) to the designated person and the designated person determines if the individual should be excluded from the compounding area (797-3).

Compliant

Prior to entering the compounding environment, personnel remove any items that are not easily cleanable or that are not necessary for compounding, unless identified below (797-3.1). Identify any requirement which is not compliant:

Entry into compounding area is compliant

Hand hygiene process is compliant, unless identified below (797-3.2). Identify any aspect that is not compliant:

Hand hygiene process is compliant

Hands are sanitized with alcohol-based hand rub before donning sterile gloves (must be donned in classified room or SCA), unless identified below (797-3.2). Identify any noncompliance:

Hand sanitizing is compliant

Garbing requirements are compliant, unless identified below (797-3.3). Identify any noncompliance:

Garbing requirements are compliant

Use of gloves is compliant, unless identified below (797-3.3). Identify any noncompliance:

Use of gloves is compliant

Does the licensee compound with HDs?

N/A

Already assessed with nonsterile HD

Media-Fill Testing (MFT)

2 flagged

All compounding personnel have documented competency before compounding CSPs by successful completion of MFT initially and every 6 months (797-2.3).

Compliant

MFT is compliant, unless identified below (797-2.3). Identify any noncompliance:

At completion of MFT, containers are incubated at 20-25C (68-77F) for 7 days then 30-35C (86-95F) for 7 days

MFT are currently being incubated at 25-35 degrees C for 14 days instead of the two required intervals

Results of evaluations and corrective actions, if failed (visible turbidity/visual manifestations of growth within 14 days), are documented and documentation is compliant, unless identified below (797-2.3). Identify element missing:

For incubation, the starting temperatures for each interval, dates of incubation, and results

Facility / Equipment

2 flagged

SCA or ante-room/buffer room are separated from areas not directly related to compounding (797-4).	Compliant
All CSPs are prepared in an ISO Class 5 or better PEC (797-4.1).	Compliant
Sterile compounding area is a well-lighted and comfortable working environment (797-4.2).	Compliant

Category 1 in SCA

Does the licensee only compound Category 1 CSPs within a SCA?	No

Category 1 or 2 in Cleanroom Suite

1 flagged

Does the licensee compound Category 1 or 2 CPSs within a cleanroom suite?	Yes
The ante-room is compliant, unless identified below (797-4). Identify any items which are not compliant:	The ante-room is compliant
The buffer room is compliant, unless identified below (797-4). Identify any items which are not compliant:	The buffer room is compliant
The cleanroom suite is compliant, unless identified below (797-4). Identify any noncompliance:	All surfaces in the classified areas are smooth, impervious, free from cracks and crevices, and non-shedding (797-4.3)

Observed what appears to be rust on carts in the sterile buffer room and anteroom which is considered an insanitary condition

The cleanroom suite is compliant with placement and movement of materials, unless identified below (797-4.5). Identify any noncompliance:	The cleanroom suite is compliant
The cleanroom suite is compliant with documented requirements, unless identified below (797-4). Identify any noncompliance:	Documented requirements are compliant for the cleanroom suite

Primary engineering control

The PEC is certified ISO Class 5 or better under dynamic operating conditions (797-4.2).	Compliant
If the PEC is used to meet the ACPH minimum in the buffer room, it runs continuously (797-4.2).	Compliant
The PEC is compliant for placement and movement of materials, unless identified below (797-4.5). Identify any items not compliant:	The PEC is compliant

Does the licensee use a laminar airflow system (LAFS) (such as LAFWs, IVLFZs, BSCs)?	Yes
LAFS are located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns inside the PEC (797-4.2).	Compliant
Does the licensee use a IVFLZ?	No
Does the licensee use a Restricted-access barrier system (RABS) (such as CAI, CACI)?	No
Does the licensee use a Pharmaceutical isolator?	No

HDs

Does licensee compound with HDs? (If already reviewed in non-sterile section, select N/A)	N/A

Certification / recertification

1 flagged

The compounding facilities (PEC, SEC) are certified initially, at least every 6 months, and after any redesign, construction, replacement or relocation of any PEC, under dynamic conditions, and certification includes all required components, unless identified below (797-5). Identify any areas missing:	Certification is complete
The licensee has implemented and documented a corrective action plan in response to any out-of-range results with review of data collected to confirm that the actions taken were effective (797-5).	N/A

None to review from last report

The licensee has developed and implemented a compliant monitoring program for total airborne particles, unless identified below (797-5.1). Identify any noncompliance:	Particle monitoring program is compliant

Per certification company

The licensee has developed and implemented a compliant microbial air and surface monitoring program, unless identified below (797-6.1). Identify any noncompliance:	Microbial air and surface monitoring program is compliant

Active air per certification company

The licensee is compliant in its sampling procedures for viable airborne particles, unless identified below (797-6.2). Identify any areas not compliant:	The sampling procedures are compliant
The licensee is compliant in its surface sampling procedures for viable particles, unless identified below (797-6.3). Identify any areas not compliant:	Samples must be inverted, incubated at 30-35°C at least 48 hrs, reviewed for CFU, incubated at 20-25°C at least 5 days,

reviewed for CFU (or follow the alternative procedure identified in Box 6-1)

Bacterial and fungal media samples used for SS; Fungal media being incubated at 26-30 C for 7 days instead of 20-25 C. Bacterial media compliant at 30-35 C x 72 hours

Cleaning / disinfecting

Licensee is compliant with cleaning and disinfecting requirements, unless identified below (797-7, 797-7.2). Identify any areas not compliant:

Cleaning and disinfecting is compliant

Using TB1, peridox and sterile 70% IPA

Licensee performs compliant daily cleaning and disinfecting, unless identified below (Table 8). Identify any aspect missing from documentation:

Daily cleaning / disinfecting is compliant

Licensee performs compliant monthly cleaning and disinfecting, unless identified below (Table 8). Identify any aspect missing from documentation:

Monthly cleaning and disinfecting is compliant

Licensee performs compliant monthly sporicidal application, unless identified below (Table 8). Identify any aspect missing from documentation:

Monthly sporicidal application is compliant

Items are wiped with a sporicidal agent, EPA-registered disinfectant, or 70% SIPA using low-lint wipers (which does not render the product label unreadable) by personnel wearing gloves before bringing the item(s) into the clean side of the ante-room, into a pass-through, or into the SCA perimeter and agent allowed to dwell or alcohol to dry (797-8.1).

Compliant

Items are wiped with 70% SIPA using low-lint wipers (which does not render the product label unreadable) prior to placement in the PEC and allowed to dry before use (unless the sterile item is received in a sealed container, it may be removed from the covering as the supply is introduced into the PEC) (797-8.2).

Compliant

Critical sites (vial stoppers, ampule necks, IV bag septums) are wiped with 70% SIPA in the PEC and allowed to dry before use (797-8.3).

Compliant

Equipment brought into classified areas is wiped with a sporicidal agent, EPA-registered disinfectant, or 70% SIPA using low-lint wipers, is placed in a manner that facilitates sterile compounding operations, and is capable of operating properly and within required performance parameters (797-9.1).

Compliant

If used, an automated compounding device (ACD) is used compliantly, unless identified below (797-9.1). Identify any area not compliant:

ACD use is compliant

Supplies (beakers, utensils, needles, syringes, filters, tubing sets) in direct contact with CSPs must be sterile and depyrogenated (797-9.2).	Compliant
Components	
The licensee's use of APIs is compliant, unless identified below (797-9.3). Identify any non-compliance:	API use is compliant
The licensee's use of components (other than APIs) is compliant, unless identified below (797-9.3). Identify non-compliance of components:	Component use is compliant
The licensee does not compound with components labeled "not for pharmaceutical use," "not for injectable use," "not for human use," or an equivalent statement (797-9.3).	Compliant
The licensee has a COA or other documentation showing conformance with established specifications for each lot of commercially available sterile, depyrogenated containers and container-closure systems (797-9.3).	Compliant
The licensee examines the external packaging of each lot of component received for evidence of deterioration and other aspects of unacceptable quality, verifies the labeling and condition of the component, and when a component is found to be of unacceptable quality, promptly rejects, labels as rejected, and segregates the component to prevent use as as well as examines other lots of the component from that vendor (797-9.3).	Compliant
Components which lack a vendor expiration date are clearly marked with the date of receipt by the licensee and have been assigned a conservative expiration date not exceeding 1 year from the date of receipt (797-9.3).	N/A
The licensee examines components before use to ensure correct identity, appropriate quality, within expiry, and have been stored under appropriate conditions and when a component is found to be unacceptable for use, promptly rejects, labels as rejected, and segregates the component as well as examines other lots of the component from that vendor (797-9.3).	Compliant
Components are handled and stored in a manner that prevents contamination, mix-ups, and deterioration (797-9.3).	Compliant
Components are stored in closed containers under temperature, humidity, and lighting conditions consistent with the official monograph or specified by the supplier/manufacturer (797-9.3).	Compliant

The temperature of the component storage area is monitored manually at least once daily or by continuous recording device with results documented and retrievable (797-9.3).	Compliant
If used, temperature monitoring devices are calibrated or verified for accuracy as recommended by the manufacturer or at least every 12 months if not specified by the manufacturer (797-9.3).	Compliant
Conventionally manufactured single-dose vials opened/punctured in an ISO Class 5 or better environment are used for no more than 12 hrs as long as the storage requirements are maintained (797-15.1).	N/A
Conventionally manufactured single-dose ampules opened/punctured are not stored for any time period (797-15.1).	N/A
Conventionally manufactured multi-dose containers opened/punctured are used for no more than 28 days unless otherwise specified by the manufacturer's labeling (797-15.2).	Compliant
Pharmacy bulk packages are punctured in an ISO Class 5 PEC and used according to manufacturer labeling (797-15.3).	Compliant
Does the pharmacy use CSPs as components?	Yes
Use of single-dose CSPs or CSP stock solutions as components to compound additional CSPs is compliant, unless identified below (797-16.2). Identify any noncompliance:	Use of component CSPs is compliant
Does the pharmacy compound with HDs? (If reviewed under non-sterile section, select N/A)	N/A

Sterilization / depyrogenation

Does the licensee perform sterilization on CSPs from non-sterile components or on containers or container-closure systems?	Yes
Sterilization methods take into account the components and the container closure systems and ensure sterility of the product without affecting the physical/chemical stability or package integrity (797-10).	Compliant

Only through filtration

Terminal sterilization (dry heat, steam, irradiation) is used unless the CSP or container/closure cannot tolerate it (797-10).	N/A

Steam sterilization is not used if the moisture, temperature and pressure would degrade the CSP or if there is insufficient moisture to sterilize the CSP (797-10).	N/A

Have just received their autoclave back after 6 months of repairs; not currently using but may plan to use in the future to sterilize eye drops

Filtration is not used for suspensions if the suspended drug particles are removed by the filter used (797-10).	Compliant
Terminal sterilization achieves an adequate sterility assurance level (797-10).	N/A
Compounded injections that contain nonsterile components or come into contact with nonsterile devices are sterilized within 6 hours of completing the preparation (797-10).	Compliant
If licensee performs sterilization or depyrogenation of supplies or container-closure systems, the efficacy of each process is established and documented per USP <1229> (797-9.3).	N/A
If the licensee prepares Category 2 CSPs from nonsterile components, presterilization procedures are completed in ISO Class 8 or better and in single-use containment glove bags, containment ventilated enclosure (CVE), BSC, or CACI which are certified at least every 6 months (797-4.2).	Compliant
Does the licensee perform depyrogenation?	No
Does the licensee perform sterilization by filtration?	Yes
Sterilizing filters are compliant, unless identified below (797-10.2). Identify any item of noncompliance:	Sterilizing filters are compliant
Filters are evaluated, per formulation, to be chemically and physically compatible with all components of the CSP, are stable at the pressure and temperatures used, and have sufficient volume capacity (797-10.2).	Compliant
Each filter used is subjected to a filter integrity test (797-10.2).	Compliant
Formulations with excessive particulate matter are pre-filtered using a larger filter (e.g., 1.2µm) or this filter is placed upstream of the sterilizing filter (797-10.2).	N/A
Any CSP prepared with a filter that fails the integrity test is filtered no more than one additional time or is discarded (797-10.2).	Compliant
Does the licensee perform sterilization by steam heat?	No

not currently

Does the licensee perform sterilization by dry heat?	No
Records / Labeling / BUDs	1 flagged
All required records are legible and stored in a manner to prevent deterioration and/or loss (797-20).	Compliant
All required compounding records for a particular CSP (Master Formulation, Compounding, release testing results) are readily retrievable for at least 3 years from the date of preparation (797-20).	Compliant
Master Formulation Records	1 flagged
Licensee maintains compliant Master Formulation Records for all CSPs compounded for more than 1 patient or for CPSs prepared from nonsterile components, unless identified below (797-11.1). Identify any aspect of the MFR missing:	Type and size of container-closure system(s)

Reviewed phentolamine, papaverine, alprostadil injection (Trimix) MFR - packaging and directions are for a 10 ml vial for multidose use but current process is to fill 5 - 1ml vials per batch to align with USP 797 revision changes.

Compounding Records	
Licensee maintains Compounding Records for all CSPs compounded, unless identified below (797-11.2). Identify any aspect of the Compounding Record missing:	Compounding records are compliant
Labeling	
CSP labeling is legible and compliant, unless identified below (797-13). Identify any element missing:	Labeling information is compliant
CSP labeling is verified to ensure it conforms with the prescription/medication order, the MFR (if required), and the compounding record (797-13).	Compliant
CSP labeling is compliant with 657 IAC 20.19 (797-13).	Compliant
Labeling processes of HD compounded preparations do not introduce contamination into the non-HD handling areas (800-11.1).	Compliant
BUDs / Storage	
For Category 1 CSPs, the BUD does not exceed 12 hrs at controlled room temp (20-25°C) or 24 hrs under refrigeration (2-8°C) (797-Table 12).	N/A
For aseptically processed Category 2 CSPs prepared from one	Compliant

or more nonsterile components, in the absence of successful sterility testing, the BUD does not exceed 24 hrs at controlled room temp (20-25°C), 4 days under refrigeration (2-8°C), or 45 days frozen (-25 to -10°C) (797-Table 13).	
For aseptically processed Category 2 CSPs prepared only from sterile components, in the absence of successful sterility testing, the BUD does not exceed 4 days at controlled room temp (20-25°C), 10 days under refrigeration (2-8°C), or 45 days frozen (-25 to -10°C) (797-Table 13).	Compliant
For aseptically processed Category 2 CSPs with successful sterility testing, the BUD does not exceed 30 days at controlled room temp (20-25°C), 45 days under refrigeration (2-8°C), or 60 days frozen (-25 to -10°C) (797-Table 13).	N/A
For terminally sterilized Category 2 CSPs, in the absence of successful sterility testing, the BUD does not exceed 14 days at controlled room temp (20-25°C), 28 days under refrigeration (2-8°C), or 45 days frozen (-25 to -10°C) (797-Table 13).	N/A
For terminally sterilized Category 2 CSPs with successful sterility testing, the BUD does not exceed 45 days at controlled room temp (20-25°C), 60 days under refrigeration (2-8°C), or 90 days frozen (-25 to -10°C) (797-Table 13).	N/A
A shorter BUD is assigned when the known chemical or physical stability is less than the time given by USP for microbial stability in Table 12 or Table 13 (797-14.3).	Compliant
BUDs are not extended beyond the limits identified in Table 12 or Table 13, regardless of literature or stability/sterility test documentation (797-14.3).	Compliant
Refrigerated or frozen products / container-closure systems are verified to be physically and chemically compatible with that storage (797-14.2.4).	Compliant
Frozen products, once thawed, are not re-frozen (797-14.2.4).	Compliant
BUDs are adjusted when the storage conditions change (freezer to refrigerator, etc.) and not additive (797-14.2.4).	Compliant
The licensee is compliant in its compounding of multiple-dose CSPs, unless identified below (797-14.4, 797-16.1). Identify any aspect of noncompliance: Multi-dose eye drops compliant with 14.5	Compounding of multi-dose CSPs is compliant
The BUD of a CSP prepared from one or more compounded components does not exceed the shortest BUD of any of the individual starting components (797-16).	Compliant

The batch size for any CSPs requiring sterility testing do not exeed 250 final yield units (797-14.2.3).	N/A
For aseptically processed, sterility tested, and passing all applicable tests for Category 3 CSPs, the BUD does not exceed 60 days at controlled room temp (20-25°C), 90 days under refrigeration (2-8°C), or 120 days frozen (-25 to -10°C) (797-Table 14).	N/A
For terminally sterilized, sterility tested, and passing all applicable tests for Category 3 CSPs, the BUD does not exceed 90 days at controlled room temp (20-25°C), 120 days under refrigeration (2-8°C), or 180 days frozen (-25 to -10°C) (797-Table 14).	N/A
Each Category 3 CSP is sterility tested; meets the requirements of USP Chapter <71> or a validated, noninferior alternative method; and, if required, endotoxin tested for acceptable results (797-14.4.4).	N/A
The Category 3 CSP BUD is supported by stability data (obtained using a stability-indicating analytical method that is able to distinguish the active ingredient from its degradants and impurities) and quantify the amount of the active ingredient (USP 14.4.3).	N/A
The Category 3 CSP is compliant with the stability data in that: 1) it is prepared according to the exact formulation from which the stability data are derived; 2) it is packaged and stored in a container closure of the same materials of composition as that used in the study; 3) the analytical method is validated based on characteristics such as those described in USP <1225>; 4) the compounding facility has documentation of the stability study, including a description of the methodology, validation of the method, the stability-indicating analytical method, and all of the study results (USP 14.4.3).	N/A
Each Category 3 CSP that is an injection or ophthalmic solution is tested for particulate matter once per formulation with acceptable results (USP 14.4.3).	N/A
Once for each formulation and for each container closure system in which it will be packaged, the container closure system used is evaluated for and conforms to container closure integrity to the end of the BUD (USP 14.4.3)	N/A

Verification / QA

Verification

The licensee completes compliant visual inspection of all CSPs at the completion of compounding, before release and dispensing, unless identified below (797-12.1). Identify any	Visual inspection of CSPs is compliant

noncompliance:	
CSPs with observed defects are discarded, or marked and segregated from acceptable units in a manner that prevents them from being release or dispensed and the defect is investigated to determine the cause (797-12.1).	Compliant
Does the licensee compound Category 2 CSPs that require sterility testing per BUD (Table 11)?	N/A
Does the licensee compound Category 2 injectable CSPs from one or more nonsterile components (for humans or animals) that require sterility testing per BUD (Table 13)?	No
Quality Assurance / Quality Control	
The licensee has formal, written QA and QC programs which are compliant, unless identified below (797-18). Identify aspects which are missing:	QA and QC programs contain the required elements
The QA and QC programs are reviewed (and the review documented) at least every 12 months by the designated person(s) and appropriate action taken if needed (797-18).	Compliant
If the licensee dispensed/administers CSPs before the results of release testing are known, compliant procedures are in place to immediately notify the prescriber(s) of a failure of specifications with the potential to cause patient harm (sterility, strength, purity, bacterial endotoxin, or other quality attributes) and determine whether a recall is necessary (797-18.1).	N/A
Implementation of recall procedures is documented (797-18.1).	Compliant
A designated person reviews all complaints (797-18.2).	Compliant
If a complaint is determined to indicate a potential quality problem with a CSP, the licensee completes a compliant investigation (797-18.2). Identify any aspect of an investigation missing:	Investigative procedures are compliant
Complaint and investigation records are readily retrievable (written or electronic) and contain all required elements, unless identified below (797-18.2). Identify any missing elements:	Complaint and investigative records are compliant
A CSP that is returned in connection with a complaint is quarantined until it is destroyed after completion of the investigation (797-18.2).	Compliant
Adverse events potentially associated with the quality of CSPs are reported in accordance with licensee SOPs.	Compliant

CSP Handling, Storage, Packaging, Shipping, Transport

Storage of CSPs is compliant to ensure CSP quality, unless identified below (797-19.1). Identify any noncompliance:	Storage of CSPs is compliant
Packaging materials protect CSPs / HDs from damage, leakage, contamination, degradation, and adsorption (797-19.2, 800-11.2).	Compliant
Licensee selects shipping containers based on product specifications, vendor information, and mode of transport (797-19.3).	Compliant
Light-sensitive CSPs are packaged in light-resistant packaging; temperature sensitive CSPs are packaged accordingly (797-19.3).	Compliant
Appropriate modes of transport are selected for CPSs and special handling instructions are included on the exterior of the transport container (797-19.3).	Compliant
Does the licensee transport HDs (compounded or otherwise)?	N/A

Spills / Disposal

Does the licensee compound with HDs?	N/A

previously reviewed

Allergens

Does the licensee engage in the compounding of allergen extracts?	No

Blood-derived / biological materials

Does the licensee compound using blood-derived or other biological materials (e.g.: HCG; Somatropin; DTE such as Armour Thyroid, NP Thyroid, Nature-Throid, and Natural Thyroid; hyaluronidase; Insulin; Pancrelipase)?	No

Administration of HDs

Does the licensee engage in the administration of HDs?	No
Does this licensee dispense/distribute compounded sterile preparations to patients in other states?	No

IA BOP Survey of Findings & POC

NuCara Pharmacy – Coralville

Compounding - Nonsterile / Sterile / HD

Onsite Inspection: 4/22/25 by Britney Origer

Contents

Sterile Compounding..... 1

Sterile Compounding

Standard	Plan of Correction	Training	Date of	Title

				(Individual responsible for correction)
2.2	**Gloved fingertip/thumb sampling is compliant, unless identified below (797-2.2). Identify any element missing or not compliant:** Samples are incubated (inverted) at 30-35C (86-95F) for min. 48 hrs then 20-25C (68-77F) for min. 5 days. CFU counts must be documented per hand. This has been updated on the GFT log.		07/28/2025	Chris Petersen, PharmD
2.2	**Result of evaluations and corrective actions, if failed (from visual observation or GFT sampling), are documented and documentation is compliant, unless identified below (797-2.2). Identify any element of documentation missing:** For incubation, the starting temperatures for each interval, the dates of incubation, and the results are now documented on the GFT sample log.		07/28/25	Chris Petersen, PharmD
2.3	**MFT is compliant, unless identified below (797-2.3). Identify any noncompliance**: MFT are currently being incubated at 25-35 degrees C for 14 days instead of the two required intervals. At completion of MFT, containers are incubated at 20-25C (68-77F) for 7 days then 30-35C (86-95F) for 7 days. This has been updated on the Media Fill log.		07/28/25	Chris Petersen, PharmD
2.3	**Results of evaluations and corrective actions, if failed (visible turbidity/visual manifestations of growth within 14 days), are documented and documentation is compliant, unless identified below (797-2.3). Identify element missing:** For incubation, the starting temperatures for each interval, dates of incubation, and results have been updated on the Media Fill Log.		07/28/25	Chris Petersen, PharmD
4.3	**The cleanroom suite is compliant, unless identified below (797-4). Identify any noncompliance**:		07/28/25	Chris Petersen, PharmD

	We removed 4 rusted tables from the clean room and replaced them with galvanized stainless-steel tables. Also Replaced rusted screws on the passthrough door handles. All surfaces in the classified areas are smooth, impervious, free from cracks and crevices and non-shedding.		
6.3	**The licensee is compliant in its surface sampling procedures for viable particles, unless identified below (797-6.3). Identify any areas not compliant:** Fungal media was incubated at 26-30 C for 7 days instead of 20-25 C. Bacterial media is compliant at 30-35 C x 72 hours. Samples must be inverted, incubated at 30-35°C at least 48 hrs, reviewed for CFU, incubated at 20-25°C at least 5 days and reviewed for CFU. This has been updated on the Surface Sample log.	07/28/25	Chris Petersen, PharmD
11.1	**Licensee maintains compliant Master Formulation Records for all CSPs compounded for more than 1 patient or for CPSs prepared from nonsterile components, unless identified below (797-11.1). Identify any aspect of the MFR missing:** Reviewed phentolamine, papaverine, alprostadil injection (Trimix) MFR - packaging and directions are for a10 ml vial for multidose use. Our current process is to fill #5 – 5ml amber vials with 1mL in each vial per batch to align with USP 797 revision changes and has been updated in each trimix MFR.	07/28/25	Chris Petersen, PharmD

IOWA BOARD OF PHARMACY

6200 PARK AVENUE, SUITE 100
DES MOINES, IA 50321-1270
515/281-5944 FAX 515/281-4609
https://pharmacy.iowa.gov

2026

General Pharmacy License No. 5971

ISSUED 03/26/2026 **EXPIRES** 12/31/2026

STATUS: Current/Active

MUST BE CONSPICUOUSLY DISPLAYED IN LOCATION TO WHICH IT APPLIES

MAILING ADDRESS

Medicap Compounding Center - Coralville
1900 James St Suite 10-B
Coralville IA 52241

LICENSED LOCATION

Medicap Compounding Center - Coralville
1900 James St Suite 10-B
Coralville IA 52241

Christopher David Petersen , Pharmacist in Charge

COUNTY 52

Iowa Board of Pharmacy

6200 Park Avenue, Suite 100
Des Moines, IA 50321-1270
(P): (515) 281-5944 (F): (515) 281-4609
Website: https://pharmacy.iowa.gov

VERIFICATION OF IOWA PHARMACY LICENSE FOR THE BUSINESS LISTED BELOW:

This is a primary source verification.

Name :	Medicap Compounding Center - Coralville
License No :	5971
License/Registration Type :	Pharmacy
Sub Type :	General Pharmacy
Date Issued :	04/01/2026
Expiration Date :	12/31/2026
Status :	Current/Active
Last Application Date :	03/26/2026
Address :	1900 James St Suite 10-B Coralville IA 52241
Pharmacist in Charge :	Christopher David Petersen,Christopher David Petersen
Disciplinary Action :	No

Anne Schlepphorst,Executive Director, Iowa Board of Pharmacy. **Date:** 07/06/2026

4MM

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☒ Nuclear ☐ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

PharmaLogic Cincinnati, LLC is 100% owned by PharmaLogic Holdings Corp, is not publicly traded and does not have shareholders.

Section 1: General Information

Pharmacy Name: PharmaLogic Cincinnati, LLC

Physical Address: 200 Albert Sabin Way, Rm G310

City: Cincinnati State: OH Zip: 45267

Mailing Address (if different from physical address): same as physical address

City: _____ State: _____ Zip: _____

Telephone: 513-872-4982 Toll Free # (NAC 639.708, NRS 639.23286): 877-688-4991

Fax: 513-342-2079 Contact Email: CincinnatiPharmacy@radiopharmacy.com

Website: www.radiopharmacy.com

Nevada Business License # (if applicable) N/A; new license application

Supervising/Managing Pharmacist Name (NRS 639.220): Cameron Grahl

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24812

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Cameron Grahl	NV Pharmacist Registration #: 24812
Name: Ellen Bowen	NV Pharmacist Registration #: 24646
Name: Grace Bowen	NV Pharmacist Registration #: 24444
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: Jessica Comstock	Credentials: PharmD	%: 0
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): PharmaLogic Holdings Corp

Corporation/Organization Name: PharmaLogic Cincinnati, LLC

Mailing Address: 200 Albert Sabin Way, Rm G310

City: Cincinnati State: OH Zip: 45267

Telephone: 513-872-4982 Email: CincinnatiPharmacy@radiopharmacy.com

Contact Person Name: Payton Hanby

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ■ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the VP Pharmacy Q&R (title) for PharmaLogic Cincinnati, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Jessica Comstock

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

2/12/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jessica Comstock

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

2/12/2026
Date

Board Use Only	Date Received: 3/16/26	Amount: $5000 CK 1013 09

Ownership



PharmaLogic Holdings Corp

5301 N. Federal Hwy, Suite 280
Boca Raton, FL 33487
(561) 416-0085

Etienne Montagut, President & CEO
[redacted]
Newton, MA [redacted]
[redacted]
DOB [redacted]
No Medical Professional License
0% Ownership

Mark Dmytruk, CFO
[redacted]
Boston, MA [redacted]
[redacted]
DOB [redacted]
No Medical Professional License
0% Ownership

Jessica Comstock, VP of Pharmacy Quality & Regulatory
[redacted]
Delphi, IN [redacted]
[redacted]
DOB [redacted]
Licensed Pharmacist
0% Ownership

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PHARMALOGIC CINCINNATI, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINTH DAY OF JULY, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PHARMALOGIC CINCINNATI, LLC" WAS FORMED ON THE TWENTY-SECOND DAY OF SEPTEMBER, A.D. 2020.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

3723214 8300

SR# 20262123750

Authentication: 204476501

Date: 07-09-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler PharmaLogic Cincinnati, LLC
Pharmacy/Wholesaler License # (if applicable) N/A; new license application
Physical Address 200 Albert Sabin Way, Rm G310
City Cincinnati State OH Zip 45267
Mailing Address (if different from physical address) same as physical address
City _____ State _____ Zip _____
Telephone 513-872-4982 Website www.radiopharmacy.com
Licensing Company Email CincinnatiPharmacy@radiopharmacy.com

Section 2: Personal Information

First Cameron Middle Jane Last Grahl
Alias(es, nicknames, name changes, etc.) _____
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X
Mailing Address [redacted]
City Cincinnati State OH Zip [redacted]
Telephone [redacted] Email [redacted]
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Missouri-Kansas City		09/16 to 05/21	
Address	**City**	**State**	**Zip**
2464 Charlotte St.	Kansas City	MO	64108
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of Missouri		09/13 to 05/16	
Address	**City**	**State**	**Zip**
510 Lewis Hall	Columbia	MO	65211
Diploma/Degree obtained, if any			
N/a			

School Name		From - To (MM/YY – MM/YY)	
Rock Bridge High School		09/09 to 05/13	
Address	**City**	**State**	**Zip**
4303 S. Providence Road	Columbia	MO	65203
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]	City	State	[redacted]
10/24 to Current		Cincinnati	OH	
04/23 to 10/24		Cincinnati	OH	
07/18 to 04/23		Columbia	MO	
01/18 to 07/18		Columbia	MO	
05/17 to 01/18		Columbia	MO	
01/15 to 05/17		Columbia	MO	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
PharmaLogic Cincinnati, LLC			11/22 to current	
Business Address		**City**	**State**	**Zip**
200 Albert Sabin Way, Rm G310		Cincinnati	OH	45267
Phone	**Title**		**Number of Employed Hours**	
513-872-4982	Pharmacist-in-Charge		6400	
Description of Duties				
Established pharmacy workflows for new products including scheduling, personnel and supplies. Established radiation safety program including developing daily procedures for compliance and maintaining records.				

Business Name			From - To (MM/YY – MM/YY)	
Essential Isotopes			11/21-11/22	
Business Address		**City**	**State**	**Zip**
1513 Research Park Cir		Columbia	MO	65201
Phone	**Title**		**Number of Employed Hours**	
573-882-0245	Staff pharmacist, then pharmacy manager		2080	
Description of Duties				
Managed staff pharmacists, pharmacy technicians and drivers. Invoiced and managed billing for customers within our network. Oversaw daily pharmacy operations, ensuring compliance with federal, state and local regulations.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

01/29/26
Date

I, Cameron Grahl, **certify that as the designated representative for**

PharmaLogic Cincinnati, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. (CG) I am at least 21 years of age;
3. (CG) I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. (CG) I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. (CG) I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. (CG) I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. (CG) I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Cameron Grahl

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/29/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cameron Grah

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/29/26

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Hamilton

I, **Cameron Grahl**, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01/29/26

Date

Subscribed and Sworn to before me this 29 day of January, 2026

Notary Public Signature

NICOLE JENNINGS, NOTARY PUBLIC
COMM. EXP. NOV. 19, 2027
STATE OF OHIO

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: PharmaLogic Cincinnati, LLC

NV Pharmacy or Outsourcing facility license # (if applicable): N/A; new license application

Physical Address: 200 Albert Sabin Way, Rm G310

City: Cincinnati State: OH Zip: 45267

Mailing Address (if different from physical address): same as physical address

City: _____ State: _____ Zip: _____

Telephone: 513-872-4982 Toll Free # (NAC 639.708, NRS 639.23286): 877-688-4991

Fax: 513-342-2079 Contact Email: CincinnatiPharmacy@radiopharmacy.com

Website: www.radiopharmacy.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Cameron Grahl

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24812

Name of Designated Person(s) as defined by revised USP-797 guidelines: Cameron Grahl

Email of Designated Person(s): cgrahl@radiopharmacy.com

Telephone of Designated Person(s): 573-823-3884

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

   ■ Category 1 ☐ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☐ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes No

5. When was the most recent certification for the ISO classified areas? November 4-5, 2025

6. What is the frequency of the recertification for the ISO classified areas? every 6 months at minimum

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ☐ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? Yes No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? At least monthly internally; completed every 6 months by an external vendor

10. Will you be performing sterile hazardous drug compounding? Yes ■ No

If you marked "**Yes**", you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

F-18 Flyrcado
F-18 Pylarify

12. What laboratory performs your sterility or endotoxin testing?

Name: N/A

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

13. What is your procedure for visual inspection of compounded sterile products?

All products are inspected before and after preparation for any visible particles, abnormal coloration, and/or turbidity. If the product does not pass visual inspection, the product is quarantined and the compounding pharmacist will reach out to the Quality and Regulatory Department for next steps/to initiate investigations as needed.

14. How often do you perform glove fingertip and medial fill testing?

In triplicate as part of the onboarding process, then annually thereafter.

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Please see SOP 6.02 - Aseptic Qualifications, 6.03 - Gowning, Garbing, and Hand Hygiene, and 7.05 - Network Training for our initial and annual training program for all personnel performing sterile compounding.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Please see SOP 6.04 - Cleaning of Clean Rooms and SRPAs and 6.05 - Cleaning of Clean LFHs and BSCs for the cleaning of our primary and secondary engineering controls, including frequency and names of approved agents used as cleaners/disinfectants and sporicidals.

17. Who performs the sterile compounding process at your facility?

Authorized nuclear pharmacists (ANPs) perform the sterile compounding process at PharmaLogic Cincinnati, LLC.

18. Who is responsible and accountable for the sterile compounding process at your facility?

Cameron Grahl, Pharmacist-in-Charge

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

All products that are delivered/shipped follow DoT regulations and emergency procedures for handling radioactive materials. The delivery process is either initiated after quality control tests are completed, or delivered under quarantine and only released to the customer upon the successful completion of quality control tests.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A		
2. Are you complying with all USP 800 guidelines?	Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	No
5. Do you have a negative pressure buffer room at your facility?	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	No
9. If yes, list the name of the device: N/A		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers? N/A

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

N/A

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

N/A

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

N/A

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?

N/A

5. What is the frequency for completing surface sampling? N/A		
6. What is the frequency for using sporicidal agents? N/A		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Payton Hanby

Name of Person who Completed the Form

Pharmacy Regulatory Affairs Specialist

Title

Signature (copies or stamps not accepted)

03/11/2026

Date

Board Use Only	Date Received: 3/16/26	Date Approved: _____	Approved By: _____

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License 0230000021

Pharmalogic Cincinnati, Llc

200 Albert Sabin Way Rm G310
Cincinnati, OH 45267-2800
Hamilton County

Terminal - Pharmacy - Category 2

Outpatient Pharmacy Guide (Updated 4/4/25)

July 15, 2025

Written Response Required

Written Response Required Details

13.4) *Record keeping (OAC 4729:5-5-04)

7) *PRINTOUTS: Do hard copy printouts meet the requirements of the rule?

License 0230000021 - Pharmalogic Cincinnati, Llc

Full

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836
http://www.pharmacy.ohio.gov

Completed by Sarah Nash
Start 7/15/2025 10:30 AM
End 7/15/2025 2:38 PM

Organization

Name
Pharmalogic Cincinnati, Llc

License Type
Terminal - Pharmacy - Category 2

Category

License Number
0230000021

Business Type
NU - Nuclear Pharmacy

DEA Number

Responsible Person
Cameron Grahl

Hours of Operation
2a-2p M-F

Contact

Address
200 Albert Sabin Way Rm G310
Cincinnati, OH 45267-2800
Hamilton County

Primary Number
(513) 872-4982

Fax Number
(513) 342-2079

Website

Personnel

Name	Initials	Position	I.D. No.	Phone	Email
Cameron Grahl		Pharmacist			cgrahl@radiopharmacy.com

1) *Initial Inspection Information

1) Personnel conducting inspection

Observation
Compliance Specialist Sarah Nash, PharmD. RPh.

2) Were multiple inspection guides used during this inspection?

Yes

Observation
A complete copy of this inspection will include: USP 825 Inspection

Any copy of this inspection is considered incomplete if all documents listed are not available for review.

3) Facility Description

Observation
The pharmacy is a closed door nuclear pharmacy servicing both inpatients and outpatients. The pharmacy hold RAM license from the Ohio Department of Health. Prescription volume is approximately 500 per month. Drug products will be delivered directly to hospitals and clinics for immediate administration by licensed healthcare professionals.
The site is a dual site which houses both manufacturing and the preparation of nuclear pharmacy products. The majority of activity will consist of the repackaging of manufactured products. The site does not compound under USP 797 or 800 but does compound under USP 825 regulations. The site does not store controlled substances or compound with blood products.
Compounded products include: illucix, netspot (GA-68 products)
Non-sterile compounding is not performed on site.
The pharmacy employs 3 pharmacists, 2 CPhTs, and 14 delivery drivers.

4) *Does the TDDD have a valid registration issued by the Drug Enforcement Administration?

No: Category 2 and is not required

5) Is the Responsible Person present during the inspection?

Yes

6) Does the TDDD distribute dangerous drugs outside of Ohio?

Yes

Observation
The pharmacy is licensed in 39 states.

10.1) Responsible Person - Terminal Distributor (OAC 4729:5-2-01)

1) *PHARMACY: Is a Pharmacist the Responsible Person for a TDDD licensed as a pharmacy?

Yes

Observation
The responsible person shall be responsible for the practice of the profession of pharmacy, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required. The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy.

9) TDDD: Is the responsible person physically present at the location for a sufficient amount of time?

Yes

Observation
The responsible person is present M-F, no issues noted.

14) REMINDER: All licensed health professionals and Responsible Person

Observation
The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of dangerous drugs.

The responsible person is responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required.

11.1) Disposal of controlled substances (OAC 4729:5-3-01)

1) Does the facility dispose of controlled substances?

Not Applicable

Observation
No controlled substances.

11.2) *Report theft/significant loss: dangerous drug, controlled substance, drug document(OAC 4729:5-3-02)

1) *REMINDER: Theft or significant loss of dangerous drugs and drug documents

Observation
A terminal distributor of dangerous drugs shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance, including drugs in transit that were either shipped from or to the licensed location: (1) The state board of pharmacy, by telephone or other method determined by the board, immediately upon discovery of the theft or significant loss; (2) If a controlled substance, the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1301.76 (9/9/2014); (3) Law enforcement authorities pursuant to section 2921.22 of the Revised Code.

A terminal distributor of dangerous drugs shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, and law enforcement authorities of any theft or loss of uncompleted prescription blank(s) used for writing a prescription, written prescription order(s) not yet dispensed and original prescription order(s) that have been dispensed.

A terminal distributor of dangerous drugs shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, law enforcement authorities and the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1305.16 (9/9/2014) of the theft or loss of any DEA form 222.

For more information on reporting, visit: www.pharmacy.ohio.gov/theft

2) *Has the TDDD experienced any theft or significant loss of any dangerous drugs in the past 24 months?

No

11.4) Verification of licensure prior to sale or purchase (OAC 4729:5-3-04)

1) What drug distributors does the TDDD purchase from?

Observation
- Telix Pharmaceuticals, license verification performed January 2024
- AAA (Novartis gene therapies), license verification performed January 2024
- McKesson

2) PURCHASE: Has the TDDD completed an annual query of the board's online roster prior to purchase of dangerous drugs at wholesale? Warning

No

Observation
If no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of section 4729.51 of the Revised Code.
Most recent queries were conducted January 2024; no query for McKesson performed.

Corrective Action
Rule 4729:5-3-04 | Verification of licensure prior to sale or purchase. Effective 3/1/19
(A) Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the boards online roster (available on the boards website: www.pharmacy.ohio.gov) to confirm any of the following:
(1) The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code; or
(2) The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code.
B) If no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of section 4729.51 of the Revised Code.
If a licensed terminal distributor of dangerous drugs conducts a documented query at least annually and relies on the results of the query in purchasing dangerous drugs, the terminal distributor shall be deemed not to have violated section 4729.51 of the Revised Code in making the purchase.

11.6) Storage of adulterated drugs (OAC 4729:5-3-06)

1) Does the facility have expired/adulterated drugs on site?

Reminder: All adulterated drugs are to be segregated from active stock and stored no longer than one year from adulteration or expiration

Not Observed during Inspection

2) *Are adulterated drugs stored in a separate and secure area?

No adulterated drugs observed during inspection

Observation
Expired products may be used for training purposes, but are stored in a labeled bin.

11.7) Controlled substances inventory requirements (OAC 4729:5-3-07)

1) Are controlled substance inventory records maintained as required by rule?

Not Applicable: Not a Category 3 TDDD

11.9) Occasional sale and drug transfers (OAC 4729:5-3-09)

3) Does the TDDD engage in intracompany sales or transfer?

Yes: Completed by intracompany sales, which includes any transaction or transfer between any division, subsidiary, parent or affiliated or related company under the common ownership and control

11.16) Returned drugs (OAC 4729:5-3-16)

1) INPATIENT: Are returned drugs dispensed or personally furnished?

No

Observation
Returned drugs are disposed of, no issues noted.

2) INPATIENT: Are dangerous drugs dispensed in a customized patient medication package for inpatients returned to stock or re-dispensed?

No

3) OUTPATIENT: Are returned drugs returned to stock or re-dispensed?

No

Observation
Returned drugs are destroyed.

4) MANIPULATION REQUIRED: Are drugs that require further manipulation prior to administration dispensed or personally furnished again?

No

7) PICK-UP STATION: Are drugs provided via pick-up station returned for destruction or disposal?

Yes

11.17) Automated pharmacy systems (OAC 4729:5-3-17)

1) Does the TDDD have an automated pharmacy system (APS)?

No

11.18) Dangerous drug recall procedures (OAC 4729:5-3-18)

1) Does the TDDD have a written procedure for the management of drug recalls?

Yes

Observation
Staff states a written policy exists; was not evaluated during the inspection.
OAC 4729:5-3-18 | Dangerous Drug Recall Procedures | Effective 11/11/2024
(A) A terminal distributor of dangerous drugs shall develop and implement a written procedure for the management of recalls by the manufacturer for dangerous drugs stocked by the terminal distributor. Such procedures shall include, where appropriate, contacting patients to whom the recalled drug products have been dispensed or personally furnished.

2) Does the written procedure include the required elements to manage a drug recall?

Yes: An attempt is made to sequester recalled drugs no later than the next business day.

Yes: Recalled drugs are quarantined until proper disposal/destruction.

Yes: The licensee maintains records related to drug recalls.

Observation
Discussed with staff.

3) Are written procedures and records updated and maintained as necessary?

Yes

11.21) Continuous Quality Improvement Programs in Pharmacy Services (OAC 4729:5-3-22)

1) Does the pharmacy have a quality assurance program?

Yes

Observation

OAC 4729:5-3-22| Continuous Quality Improvement Programs in Pharmacy Services| Effective 3/1/2025
(A) As used in this rule, "dispensing error" or "error in dispensing" means one or more of the following discovered after the dispensation (e.g., final verification) by a pharmacist or verification in accordance with rule 4729:5-3-17 of the Administrative Code, regardless of whether the patient received the drug:

(1) Variation from the prescriber's prescription or drug order, unless otherwise modified by the pharmacist in accordance with agency 4729 of the Administrative Code, including:

(a) Incorrect drug;

(b) Incorrect drug strength;

(c) Incorrect dosage form;

(d) Incorrect patient; or

(e) Inadequate or incorrect packaging, labeling, or directions.

(2) Failure to exercise professional judgment in identifying and managing:

(a) Known therapeutic duplication;

(b) Known drug-disease contraindications;

(c) Known drug-drug interactions;

(d) Incorrect drug dosage or duration of drug treatment;

(e) Known drug-allergy interactions;

(f) Any product quality issue attributed to a compounded drug preparation;

(g) A clinically significant, avoidable delay in therapy; or

(h) Any other significant, actual, or potential problem with a patient's drug therapy related to the practice of pharmacy.

(3) Sale of a drug to the incorrect patient.

(4) Variation in bulk repackaging or filling of automated devices, including:

(a) Incorrect drug;

(b) Incorrect drug strength;

(c) Incorrect dosage form; or

(d) Inadequate or incorrect packaging or labeling.

(5) A dispensing error does not include the delivery of an incorrect drug to a patient by a pharmacy delivery agent as defined in rule 4729:5-5-22 of the Administrative Code.

(B) A "dispensing error" or "error in dispensing," as defined in paragraph (A) of this rule, may be considered a violation of division (A)(2) of section 3715.52 and section 3715.64 of the Revised Code.

(C) Each pharmacy licensed as a terminal distributor of dangerous drugs shall establish or participate in an established quality assurance program that documents and assesses dispensing errors to determine cause and an appropriate response to improve the quality of pharmacy service and prevent errors.

(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the

pharmacy to be made readily retrievable upon request of an agent, inspector, or employee of the board.

(2) The quality assurance program shall include necessary documentation, internal reporting, and assessment of dispensing errors to determine the cause and an appropriate response to prevent future dispensing errors.

(3) All records of the quality assurance program for each pharmacy shall be maintained for three years from the date of creation in a readily retrievable manner.

(4) Any record reviewed in accordance with this paragraph shall be for investigation or inspection purposes and shall be subject to confidentiality protections pursuant to section 4729.23 of the Revised Code.

(5) If applicable, a quality assurance review may be conducted by a quality assurance committee established in accordance with section 2305.24 of the Revised Code.

(D) When a pharmacy determines or has been notified that a dispensing error has occurred, a representative of the terminal distributor of dangerous drugs shall as soon as possible:

(1) Communicate to the patient or the patient's caregiver the fact that an error in dispensing has occurred, and the steps required to avoid harm or mitigate the error.

(2) Communicate to the prescriber the fact that an error in dispensing has occurred only if the error could result in potential or actual patient harm.

(3) The communication requirement of this paragraph shall only apply when a patient receives a drug that was the result of a dispensing error and the error poses harm to the patient. Harm includes impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

(4) The pharmacy shall maintain documentation that the communications requirements of this rule were completed. Such documentation shall be maintained for three years from the date of creation in a readily retrievable manner.

(E) If a pharmacy is notified of a dispensing error by the patient, the patient's caregiver, or a prescriber, a representative of the terminal distributor of dangerous drugs is not required to communicate with that individual as required in paragraph (E) of this rule.

(F) The terminal distributor of dangerous drugs shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program.

(G) Nothing in this rule shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources by a third party or administrative offices with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this rule.

(H) The pharmacy shall comply with the reporting requirements for dispensing errors pursuant to rule 4729:5-4-02 of the Administrative Code.

13.1) Definitions – outpatient pharmacies (OAC 4729:5-5-01)

1) Is the TDDD an outpatient pharmacy or does the TDDD dispense outpatient prescriptions?

Yes: Dispenses Outpatient Prescriptions

13.2.1) Minimum Standards (OAC 4729:5-5-02)

1) Does the TDDD provide sufficient tools and equipment in updated and good repair?

Yes

2) Does the TDDD provide pharmacy personnel access to the required references?

Yes: Internet access to the board's website, Ohio laws and administrative codes, code of laws of the United State of America, and code of federal regulations

Yes: Access to hard copy or internet access to appropriate pharmacy reference materials

Yes: Access of telephone number of a poison control center

Observation
Reference materials include package inserts, SDS, USP chapters, SNMI journal articles

3) Does the TDDD ensure pharmacy personnel are sufficiently trained to safely and adequately perform their assigned duties?

Yes

4) Does the TDDD maintain a stock of drugs sufficient to compound and prepare the types of prescriptions offered?

Yes

5) Does the TDDD maintain stock of prescription containers necessary to dispense drugs in accordance with federal and state laws?

Yes

6) *Does the TDDD ensure all areas where drugs and devices are stored and prepared are dry, well-lit, well-ventilated, and maintained in a clean, sanitary, and orderly condition?

Yes

7) *Are hours of operation of the pharmacy department posted?

Not Applicable: Closed-door pharmacy

8) *Are all employees of the pharmacy identified by a name tag?

Yes: Name tag includes job title

9) Does the TDDD maintain the current contact information to the security system vendor?

Yes

Observation
The security system are through Fishel.
Badge system is through Uni Identity.

10) Does the TDDD provide sufficient time for pharmacists to complete professional duties and responsibilities?

Yes

13.2.2) Provision of Ancillary Services in an Outpatient Pharmacy (OAC 4729:5-5-02.1)

1) Does the pharmacy offer ancillary services?

No

13.2.3) Mandatory Rest Breaks for Pharmacy Personnel (OAC 4729:5-5-02.2)

1) Does the pharmacy require pharmacy personnel to work longer than 13 hours in any workday?

No

Observation
Pharmacy is not open more than 12 hours.

2) Do pharmacy personnel have at least 8 hours of off time between consecutive shifts?

Yes

3) Are pharmacy personnel working longer than 6 continuous hours/workday allowed to take a 30-minute, uninterrupted rest break?

Yes

7) REMINDER: Retaliation Information

Observation
4729:5-5-02.2 Mandatory Rest Breaks for Pharmacy Personnel.
(E) An outpatient pharmacy shall not retaliate or discipline a pharmacist for refusing to work longer than thirteen hours or pharmacy personnel that opt to take breaks in accordance with this rule. As used in this rule, retaliation or discipline of an employee includes, but is not limited to, the following:
(1) Removing or suspending the employee from employment;
(2) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;
(3) Transferring or reassigning the employee;
(4) Denying the employee a promotion that otherwise would have been received;
(5) Reducing the employee in pay or position.

13.2.4) Requests for Additional Staff/Reports of Staffing Concerns in a Pharmacy (OAC 4729:5-5-02.3)

1) Does the pharmacy have a process for pharmacy staff to communicate requests for additional staff or reports of staffing concerns? Warning

No

Observation
RP not familiar with a formal process to communicate staffing concerns.

Corrective Action
Pharmacy to ensure a process exists to communicate staffing concerns.
4729:5-5-02.3 Requests for Additional Staff and Reports of Staffing Concerns in an Outpatient Pharmacy. Effective 5/1/24
(A) An outpatient pharmacy shall develop a process for pharmacy staff to communicate requests for additional staff or reports of staffing concerns. Requests for additional staff or reports of staffing concerns shall be communicated and documented by the responsible person or pharmacist on duty to the terminal distributor.
(B) Executed requests for additional staffing or reports of staffing concerns shall be provided to the immediate supervisor of the responsible person or pharmacist on duty, with one copy maintained in the pharmacy for three years for immediate inspection by an agent, inspector, or employee of the board.

2) Are all issues listed in the requests and reports of concern resolved in a timely manner?

Other: See Observation Below

Observation
4729:5-5-02.3 Requests for Additional Staff and Reports of Staffing Concerns in an Outpatient Pharmacy. Effective 5/1/24
(C) Outpatient pharmacies licensed as terminal distributors of dangerous drugs shall review all requests and reports of concern submitted in accordance with this rule and shall resolve any issues listed in a timely manner to ensure a safe working environment for pharmacy staff as required by section 4729.55 of the Revised Code. A written response to the request or report of concern shall occur within fourteen business days of submission and be communicated to the responsible person or pharmacy staff who submitted the request for additional staffing or report of concern. A copy of this response shall be maintained in the pharmacy for three years for immediate inspection by an agent, inspector, or employee of the board.

3) Has there been retaliation or discipline for requesting staff or reporting concerns?

No

Observation
4729:5-5-02.3 Requests for Additional Staff and Reports of Staffing Concerns in an Outpatient Pharmacy. Effective 5/1/24
(D) An outpatient pharmacy shall not retaliate or discipline a pharmacist who, in good faith, makes a request for additional staff or reports staffing concerns in accordance with this rule. As used in this rule, retaliation or discipline of an employee includes, but is not limited to, the following:
(1) Removing or suspending the employee from employment;
(2) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;
(3) Transferring or reassigning the employee;
(4) Denying the employee a promotion that otherwise would have been received;
(5) Reducing the employee in pay or position.

4) REMINDER: Retaliation Information

Observation
4729:5-5-02.3 Requests for Additional Staff and Reports of Staffing Concerns in an Outpatient Pharmacy. Effective 5/1/24
(D) An outpatient pharmacy shall not retaliate or discipline a pharmacist who, in good faith, makes a request for additional staff or reports staffing concerns in accordance with this rule. As used in this rule, retaliation or discipline of an employee includes, but is not limited to, the following:
(1) Removing or suspending the employee from employment;
(2) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;
(3) Transferring or reassigning the employee;
(4) Denying the employee a promotion that otherwise would have been received;
(5) Reducing the employee in pay or position.

13.2.5) Significant Delays in the Provision of Pharmacy Services (OAC 4729:5-5-02.4)

1) NEW: Are new prescriptions received by the pharmacy dispensed without significant delay?

Yes

13.3) *Filing and storage of prescriptions (OAC 4729:5-5-03)

1) *Are prescriptions maintained in three separate prescription files?

Not Applicable

Observation
No controlled substances processed by the pharmacy.

2) HARD COPY: Are non-controlled hard copy prescriptions electronically maintained?

Other: See Observation Below

Observation
Not applicable

3) Are electronically transmitted prescriptions maintained?

Yes

Observation
The EMR system, BioRx, maintains electronic prescriptions.

4) Do electronic systems used to maintain prescription images or data meet the requirements of the rule?

Yes: Contains security features to prevent unauthorized access to the records

Yes: Contains daily back-up functionality to protect against loss of records

Observation
Main server is in Boca Raton, Florida.

5) *Are all prescription records uniformly maintained for a period of three years?

Yes

13.4) *Record keeping (OAC 4729:5-5-04)

1) *DISPENSING PROCESESS: Is there positive identification for the dispensing process of a prescription, as required by rule?

See Observaations Below

Observation
BioRx does not accommodate electronic positive ID at this time; hard copy printouts are utilized at this time.
Rule 4729:5-6-01 | Definitions - nuclear pharmacies and radiopharmaceuticals. Effective 2/1/22
(M)
(1) "Positive identification" means a method of identifying a person that does not rely on the use of a private personal identifier such as a password, but must use a secure means of identification such as the following:
(a) A manual signature on a hard copy record;
(b) A magnetic card reader;
(c) A bar code reader;
(d) A biometric method;
(e) A proximity badge reader;
(f) A board approved system of randomly generated personal questions;
(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the dangerous drug. The printout must be maintained for three years and made readily retrievable; or
(h) Other effective methods for identifying individuals that have been approved by the board.
(2) A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

5) Can the record keeping systems provide immediate retrieval of the required data for all prescriptions dispensed within the previous 12 months?

Yes: Includes the original prescription number

Yes: Includes date of issuance of the original prescription order by the prescriber

Yes: Includes full name of the patient for whom the drug is intended; or, if the patient is an animal, the last name of the owner, name of animal (if applicable), and species of the animal or animals

Yes: Includes full name and address of the prescriber, including the physical address of the prescriber's practice location

Yes: Includes the prescriber's credential (MD, DDS, DVM, etc.), if indicated on the prescription

Yes: Includes directions for use

Yes: Includes the brand name, if any, or the generic name and the name of the manufacturer or distributor or national drug code of the drug or device dispensed

Yes: Includes the strength, dosage form, and quantity of the drug or device dispensed

Yes: Includes the date of dispensing

6) What method does a pharmacy that is unable to electronically document positive identification use for hard copy documentation?

Hard copy printout of each day's prescription data

7) *PRINTOUTS: Do hard copy printouts meet the requirements of the rule? Written Response Required

No

Observation

Reviewed end of day reports and the following are missing:

- data entry/data entry verification/DUR (all pharmacist steps)

Corrective Action

Pharmacy to determine how to achieve compliant end of day reports.

Rule 4729:5-5-04 | Record keeping. Effective 12/1/20

(B) All records maintained in accordance with this rule shall be uniformly maintained for a period of three years.

(D) A pharmacy that utilizes a computerized system to dispense dangerous drugs that is unable to electronically document positive identification in accordance with paragraph (A) of this rule shall be required to maintain hard copy documentation. Hard copy documentation shall be provided by each registered or licensed individual who makes use of such system by one of the following methods:
(1) A hard copy printout of each day's prescription data.
(a) The printout shall include, at a minimum, the following data:
(i) Date of dispensing;
(ii) Prescription number;
(iii) Patient name;
(iv) Name, strength, and quantity of drug dispensed;
(v) Identification of the pharmacist or pharmacy personnel responsible for any activity described in paragraph (A) of this rule;
(vi) Identification of the pharmacy; and
(vii) Identification of controlled substances.
(b) The printout must be verified, dated, and signed by each individual responsible for any activity described in paragraph (A) of this rule. The printout must be verified and manually signed by the individual within a reasonable timeframe to ensure the accuracy of the record.
(c) If the printout is prepared at a location other than where the drug was dispensed, the printout must be provided to the licensed location within three business days of the date on which the drugs were dispensed. Such printouts must be verified and signed by each individual responsible for any activity described in paragraph (A) of this rule within twenty-four hours of the date the printout is received by the individual.
(d) The printout must be readily retrievable and maintained in chronological order in a separate file at the licensed location where the drug was dispensed for a period of three years from the date of dispensing.
(e) The signed printout may be stored electronically in accordance with paragraph (E) of this rule.

(E) A signed printout that is maintained in accordance with paragraph (D) of this rule may be electronically created and maintained, provided the system creates and maintains the printout in accordance with the following:
(1) All information in the printout shall be scanned in full color (i.e. retains color information and/or color graphics in the document) via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user;
(2) A record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted;
(3) Contains security features to prevent unauthorized access to the records;
(4) Contains daily back-up functionality to protect against record loss.

13.8) *Prospective drug utilization review (OAC 4729:5-5-08)

1) Do pharmacists review the patient profile prior to dispensing a prescription?

Yes: Pharmacist completes DUR

13.10) *Manner of processing a prescription (OAC 4729:5-5-10)

3) ORAL: Do pharmacists make a record of the full name of the prescriber and prescriber's agent, if applicable, for oral prescripitons?

Yes

5) ORAL: Do certified pharmacy technicians receive oral non-controlled drug prescriptions?

No

13) REMINDER: Valid Prescription and Corresponding Responsibility

Observation
A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of the prescriber's professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.

13.14) Prescription pick-up station (OAC 4729:5-5-14)

1) PHARMACY: Does the pharmacy act as a "pick-up" station or intermediary for the purpose of having prescriptions filled?

Yes: Site is a licensed TDDD

Yes: The receipt, storage, control, and distribution of prescriptions are in the full and actual charge of a pharmacist

Yes: A record keeping system is in place that provides accountability for proper receipt, delivery, disposal and return of all prescriptions

3) PHARMACY: Does the pharmacy dispensing dangerous drugs to a "pick-up station" meet the requirements of the rule?

Yes: Site is licensed as a terminal distributor of dangerous drugs unless exempted or granted waiver by the board

Yes: There is clear and convincing evidence that delivery of a prescription medication directly to the patient would result in danger to public health or safety

Yes: There is clear and convincing evidence that delivery of a prescription medication directly to the patient would result in danger to the patient without increased involvement by a health care professional in the patient's drug therapy

13.18) Dispensing customized patient medication packages by an outpatient pharmacy (OAC 4729:5-5-18)

1) Does the pharmacy dispense customized patient medication packages?

No

13.22) *Return to stock in an outpatient pharmacy (OAC 4729:5-5-22)

1) Does the pharmacy return dispensed drugs to stock (RTS)?

No

13.23) *Security, control and storage of dangerous drugs in an outpatient pharmacy (OAC 4729:5-5-23)

1) *Does a pharmacist provide adequate supervision of the pharmacy and records? Warning

No

Observation
There are three entrances into the pharmacy space. All are accessible by badge access, held by all pharmacy staff (RPh and CPhT) as well as manufacturing staff (non-pharmacists).
The pharmacy's barricade is an alarm system, which consists of motion sensors and door contact sensors. At this time, pharmacists and management have alarm code access - **non-pharmacists have alarm codes to enter pharmacy space**. Discussed with RP, who determined removing alarm code access from non-pharmacists is the easiest method to achieve compliance.
There are multiple cameras, which are part of the badge system but are not related to the alarm.

Corrective Action
Pharmacy to ensure alarm codes are reset and only provided to pharmacists.
Rule 4729:5-5-23 | Security, control and storage of dangerous drugs in an outpatient pharmacy. Effective 12/1/20
(A) The following applies to an outpatient pharmacy licensed as a terminal distributor of dangerous drugs:
(1) Except as provided in paragraph (A)(6) of this rule, a pharmacist shall provide supervision of the dangerous drugs, hypodermics, D.E.A. controlled substance order forms, all records relating to the distribution of dangerous drugs, except where the board has granted permission for such records to be stored at a secure off-site location in accordance with this chapter of the Administrative Code, at all times in order to deter and detect theft or diversion.

(6) Whenever a pharmacist cannot meet the supervision requirements in paragraph (A)(3)(a) of this rule, security of the pharmacy must be provided in accordance with the following:
(a) The pharmacy must be secured by either:
(i) A physical barrier (i.e. barricade) with suitable locks approved by the board. Except for extraordinary circumstances

beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to a physical barrier prior to implementation.
(ii) An alarm system approved by the board that is monitored by a central station for control and can detect unauthorized access to the pharmacy. The alarm system shall be tested on a biannual basis. The pharmacy or the entity that manages security for the pharmacy shall maintain testing records for three years from the date of testing and shall make such records readily retrievable. The pharmacy shall be responsible for obtaining testing records if such records are maintained by a third-party. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to an alarm system prior to implementation. This notification requirement does not apply if a pharmacy also utilizes an approved physical barrier in accordance with paragraph (A)(6)(a)(i) of this rule.
(b) Except as provided in paragraph (A)(6)(i) of this rule, the pharmacy must contain all dangerous drugs, hypodermics, and D.E.A. controlled substance order forms and every other item or product that requires the supervision or sale by a pharmacist.
(c) Only a licensed pharmacist may have access to keys or other methods of gaining access to the pharmacy.
(i) Keys to the pharmacy that are not in the possession of a licensed pharmacist that are maintained on-site shall be secured to prevent unauthorized access.
(ii) All combinations or access codes, including alarm codes, shall be changed upon termination of employment of an employee having knowledge of the combination or access code.
(d) All records relating to the distribution of dangerous drugs must be maintained in the pharmacy, except as follows:
(i) The board has granted permission for such records to be stored at a secure off-site location in accordance with this chapter of the Administrative Code; or
(ii) Any designated area outside the pharmacy used to store records that complies with paragraph (A)(6)(i) of this rule.
(e) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the pharmacy.
(f) Only a pharmacist may have access to the pharmacy or stock of dangerous drugs or assume responsibility for the security of dangerous drugs, hypodermics, and any other item or product that requires the supervision or sale by a pharmacist.
(g) No prescription, dangerous drug, hypodermic, nor any other item or product that requires the supervision or sale by a pharmacist may be sold, given away, or disposed of at any time the pharmacy is closed.
(h) New or refill prescription orders may be deposited into a secured area within the building where the pharmacy is located when a pharmacist is not present. Only a pharmacist may have access to this secured area.
(i) Any designated area outside the pharmacy at the location licensed as a terminal distributor of dangerous drugs intending to be used for the storage of dangerous drugs, D.E.A. controlled substance order forms, hypodermics, and records relating to the distribution of dangerous drugs, except where the board has granted a permission for such records to be stored at a secure off-site location pursuant to this chapter of the Administrative Code, and every other item or product that requires the supervision or sale by a pharmacist shall meet the following requirements:
(i) The designated area shall be secured by an approved physical barrier with suitable locks to detect unauthorized entry. Except for extraordinary circumstances beyond the pharmacys control, a pharmacy shall notify the board of any installation or modification to a physical barrier prior to implementation.
(ii) No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the designated area, unless authorized by the board of pharmacy.
(iii) Authorized personnel may have access if there is supervision by a pharmacist.
(iv) No controlled substances may be stored outside of the pharmacy, except as authorized under division 4729:10 of the Administrative Code.
(j) If an outpatient pharmacy provides services by means of a drive-through facility, the drive-through facility shall be constructed and maintained in a manner, and with materials, that secures the premises of the pharmacy from unauthorized access.

(3) The pharmacist or pharmacists on duty:
(a) Shall be physically present at the licensed location and responsible for the security of the pharmacy and supervision of pharmacy personnel.
(b) If the pharmacy is located within a store or business, shall ensure that all dangerous drugs, controlled substances, and hypodermics that are delivered onto the premises of the store or business are immediately placed and secured in the pharmacy under the physical control of the pharmacist or pharmacists on duty or secured in a designated area in accordance with paragraph (A)(6)(i) of this rule.

2) Is the pharmacy separated from the merchandising or public areas?

Not Applicable: Not open to the public

3) Is a pharmacist physically present at the pharmacy?

Yes: Responsible for security of pharmacy

Yes: Supervises pharmacy personnel

4) *DELIVERIES: Are dangerous drugs and hypodermics immediately secured upon delivery?

Yes: Secured in the pharmacy

5) Is a pharmacist present at all times non-pharmacy personnel enters the pharmacy?

Yes

6) *SCHEDULE II DRUGS: Are all schedule II controlled substances stored in a securely locked, substantially constructed cabinet or safe?

Not Applicable

7) *How is the pharmacy secured when a pharmacist cannot be present?

An alarm system approved by the board

8) ALARM SYSTEM: Does the alarm system and testing meet the requirements of the rule?

Yes: It is monitored by a central station for control and can detect unauthorized access to the pharmacy

Yes: The alarm system is tested on a biannual basis.

Yes: Testing records are maintained for three years

9) Are items requiring pharmacist supervision stored outside of the pharmacy?

No

11) RECORDS: Are records relating to the distribution of dangerous drugs only maintained in the pharmacy?

Yes

12) Are any items, products, records, or equipment that must be accessible to anyone other than a pharmacist stored in the pharmacy?

No

17) *DRIVE-THRU: Does the pharmacy provide services by means of a drive-thru facility?

No: No drive-thru facilities

13.24) *Drug inventory records and other record keeping provisions (OAC 4729:5-5-24)

1) *RECEIPT: Do records of receipt contain the required information?

Yes: Contains name, strength, dosage form, and quantity of dangerous drug received

Yes: Contains name and address of seller

Yes: Contains name and address of recipient

Yes: Contains date of receipt

2) TEMPERATURE MONITORING: Do records of temperature control monitoring include the required information?

No

Observation

The pharmacy and manufacturing parts of the business share a refrigerator. At this time, the pharmacy maintains a paper log of temperatures which only account for Monday-Friday. The manufacturing business has a continuous temperature monitor and is alerted in real time to excursions.

Discussed that the manufacturing continuous monitor may be used for the pharmacy's record, but there needs to be a written policy that if manufacturing is notified of an excursion, the pharmacy staff must be made immediately aware and corresponding documentation retained for 3 years.

Rule 4729:5-5-24 | Drug inventory records and other record keeping provisions. Effective 8/19/22

(B) Temperature logs maintained in accordance with paragraph (B) of rule 4729:5-5-23 of the Administrative Code shall include either:

(1) The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded; or

(2) For automated systems that provide temperature monitoring, either of the following:

(a) A report that provides, at a minimum, the date and time of observation and the temperature recorded; or

(b) A report that provides temperature excursions, if any, and the date, time, temperature recorded, and length of the noted excursion.

Rule 4729:5-5-23 | Security, control and storage of dangerous drugs in an outpatient pharmacy. Effective 12/1/20

(B) Refrigerators and freezers used for the storage of dangerous drugs shall comply with the following:

(1) Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

(a) Temperature logs with, at a minimum, daily observations; or

(b) A temperature monitoring system capable of detecting and alerting staff of a temperature excursion.

(2) The terminal distributor shall develop and implement policies and procedures to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs.

(3) The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store dangerous drugs.

3) NON-CONTROLLED DISPOSAL: Do records of dangerous drugs disposed from inventory, other than controlled substances, contain the required information?

See Observation Below

Observation
Provided printed copy of Board's non-controlled substance disposal form.
Rule 4729:5-5-24 | Drug inventory records and other record keeping provisions. Effective 8/19/22
(C) Records of dangerous drugs disposed from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the positive identification of the licensed or registered health care professional that performed the disposal.

6) TRANSFR/SALE: Do records of transfer or sale contain the required information?

See Observation Below

Observation
Rule 4729:5-5-24 | Drug inventory records and other record keeping provisions. Effective 8/19/22
(E) Records of transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code shall contain the name, strength, dosage form, national drug code, and quantity of the dangerous drug transferred or sold, the address of the location where the drugs were transferred or sold, and the date of transfer or sale.

Rule 4729:5-3-09 | Occasional sale and drug transfers.

7) Are electronic records created and maintained in accordance to rule?

See Observation Below

Observation
Rule 4729:5-5-24 | Drug inventory records and other record keeping provisions. Effective 8/19/22
(F) All records maintained pursuant to this rule may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:
(1) Complies with the requirements of this rule;
(2) All paper records maintained electronically shall be scanned in full color via technology designed to capture all information in the paper record in one form and reproduce it in an electronic medium presentable and usable to an end user;
(3) Contains security features to prevent unauthorized access to the records; and
(4) Contains daily back-up functionality to protect against record loss.

8) *RECORDS: Are all records readily retrievable and kept on-site for at least three years?

Yes

10) *RECORDS: Do all computerized records contain daily back-up functionality to protect against record loss?

Yes

11) CONTROLLED SUBSTANCE INVENTORY: Is a controlled substance inventory completed within 13 months of the previous inventory and upon adding a scheduled drug?

Not Applicable

18.1) Definitions – pharmacy compounding (OAC 4729:7-2-01)

1) Does the pharmacy compound?

Yes: Nuclear Compounding

18.2) Sterile compounding exemptions (OAC 4729:7-2-02)

1) Does the pharmacy compound non-hazardous, conventionally manufactured sterile products in accordance with the directions contained in approved labeling provided by the product's manufacturer?

Yes

18.3) Drugs compounded in a pharmacy (OAC 4729:7-2-03)

1) Does the pharmacy compound non-sterile drug products?

No: Pharmacy does not compound non-sterile drug products

18.5) Drugs compounded for veterinarian office use (OAC 4729:7-2-05)

1) Does the pharmacy compound drugs intended for animal use by licensed veterinarians?

No

28) Substance Abuse and Mental Health Resources for Healthcare Professionals

1) Substance Abuse and Mental Health Resources for Healthcare Professionals

Observation

The healthcare profession is not immune to substance use disorder and mental health conditions. Such medical conditions impair a healthcare professional's competency, ability, and judgment. Substance use disorder and/or mental health conditions that are left untreated may not only cause a healthcare professional to risk their career, but may also endanger the life of a patient. These medical conditions can be effectively treated, and it is possible for healthcare professionals that are in treatment or recovery to return to practice.

The State of Ohio Board of Pharmacy encourages all healthcare professionals who may be struggling with substance use disorder or mental health condition to seek help. The following are resources that can assist healthcare professionals in getting help: (The resources listed here are for informational purposes only and do not constitute an endorsement by the State of Ohio Board of Pharmacy. They do not represent a complete list of the resources available)

Ohio Careline 1-800-720-9616, emotional support, with referral to other resources if needed.
Crisis text line, text "4hope" to 741 741 to speak with a crisis counselor.
Treatment Bridge 1-877-275-6364, for addiction and mental health services.
National Suicide prevention dial 988, or call 1-800-273-8255.
Ohio Domestic Violence Network 1-800-934-9840
Pharmacist Rehabilitation Organization (www.ohiopro.org) for pharmacists and pharmacy interns.
Ohio Physicians Health Program (www.ophp.org)

29) Inspection Affirmation

1) Inspection Affirmation

Observation

*This document only addresses compliance with the rules or laws specifically identified above.

As the person in charge at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent/Inspector, and understand its content.

If this inspection report requires a written response, I understand, per OAC 4729:5-3-03, that either of the following must be submitted to the State of Ohio Board of Pharmacy within 30 days of this inspection:
(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or
(2) An explanation disputing the observed violations.

I understand that if I am not the responsible person documented on this site's Ohio terminal distributor of dangerous drugs license, I will ensure the responsible person is provided a complete copy of this inspection report in a timely manner.

I further acknowledge that a written response does not release the licensee listed in this inspection report from potential disciplinary action.

Responses must be either emailed (with a copy of the inspection report) to WRITTENRESPONSE@PHARMACY.OHIO.GOV or mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

Written Response Required

Reviewed by Cameron Grahl

(signature)

Corrective Action Plan

PharmaLogic Cincinnati, LLC
OH BOP Inspection
Inspection Date: 7/15/2025

Violation 13.4, 7: PRINTOUTS: Do hard copy printouts meet the requirements of the rule?
Comments: Reviewed end of day reports and the following are missing: data entry/data entry verification/DUR (all pharmacist steps).
Response: Current daily reports do not include the aforementioned items. An additional custom report can be printed to include the missing information.

- Corrective Action: Designated Person will print out daily report after all doses have been dispensed and additional report to include data entry, data entry verification, and DUR. Designated Person will manually sign reports at the end of each day to confirm review and maintain for three years. This task will be reviewed with all staff pharmacists as part of their 'closing check list.'
- Target Completion Date: 07/25/2025

Warning 11.4, 2: PURCHASE: Has the TDDD completed an annual query of the board's online roster prior to purchase of dangerous drugs at wholesale?
Comments: If no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of section 4729.51 of the Revised Code. Most recent queries were conducted January 2024; no query for McKesson performed.
Response: Pharmacy Manager will perform an annual query of all wholesalers at the start of each calendar year. Documentation will be kept in online or electronic format for record keeping.

- Corrective Action: See above. Reminder shall be set up in BioRx alerts.
- Target Completion Date: 07/18/2025

Warning 13.2.4, 1: Does the pharmacy have a process for pharmacy staff to communicate requests for additional staff or reports of staffing concerns?
Comments: RP not familiar with a formal process to communicate staffing concerns.
Response: Process for communicating requests/concerns is available through routine staff and one-on-one meetings or at any time issues arise in the pharmacy.

- Corrective Action: Pharmacy staff routinely meets with reporting manager to discuss any work-related concerns including staffing issues. All pharmacy staff can utilize their 'chain of command' when operational issues arise (i.e., Pharmacy Staff to Pharmacy Manager, Pharmacy Manager, to Director of Pharmacy Operations, Director of Pharmacy Operations to VP of Pharmacy Operations, if necessary). All company employees may also reach out to the HR department directly. This will be reiterated to all staff members during routine meetings.
- Target Completion Date: 7/18/2025

Warning 13.23,1: Does a pharmacist provide adequate supervision of the pharmacy and records?
Comments: There are three entrances into the pharmacy space. All are accessible by badge access, held by all pharmacy staff (RPh and CPhT) as well as manufacturing staff (non-pharmacists). The pharmacy's barricade is an alarm system, which consists of motion sensors and door contact sensors. At this time, pharmacists and management have alarm code access – non pharmacists have alarm codes to enter pharmacy space. Discussed with RP, who determined removing alarm code access from non-

pharmacists is the easiest method to achieve compliance. There are multiple cameras, which are part of the badge system but are not related to the alarm.

Response: Alarm code will be changed and access removed from manufacturing staff.

- Corrective Action: *See above. Code will only be available to pharmacists.*
- Target Completion Date: 7/15/2025

State of Ohio Board of Pharmacy

77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License 0230000021

Pharmalogic Cincinnati, Llc

200 Albert Sabin Way Rm G310
Cincinnati, OH 45267-2800
Hamilton County

Terminal - Pharmacy - Category 2

USP 800 and 825 Inspection

July 15, 2025

License 0230000021 - Pharmalogic Cincinnati, Llc

Full

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836
http://www.pharmacy.ohio.gov

Completed by Sarah Nash
Start 7/15/2025 10:30 AM
End 7/15/2025 2:41 PM

Organization

Name
Pharmalogic Cincinnati, Llc

License Type
Terminal - Pharmacy - Category 2

Category

License Number
0230000021

Business Type
NU - Nuclear Pharmacy

DEA Number

Responsible Person
Cameron Grahl

Hours of Operation
2a-2p M-F

Contact

Address
200 Albert Sabin Way Rm G310
Cincinnati, OH 45267-2800
Hamilton County

Primary Number
(513) 872-4982

Fax Number
(513) 342-2079

Website

Personnel

Name	Initials	Position	I.D. No.	Phone	Email
Cameron Grahl		Pharmacist			cgrahl@radiopharmacy.com

1) *Initial Inspection Information

1) Personnel conducting inspection

Observation
Compliance Specialist Sarah Nash, PharmD, RPh

2) Were multiple inspection guides used during this inspection?

Yes

Observation
A complete copy of this inspection will include: Outpatient Pharmacy

Any copy of this inspection is considered incomplete if all documents listed are not available for review.

4) *Does the TDDD have a valid registration issued by the Drug Enforcement Administration?

No: Category 2 and is not required

5) Is the Responsible Person present during the inspection?

Yes

6) Does the TDDD distribute dangerous drugs outside of Ohio?

Yes

Observation
Licensed in 39 states

2.1) Definitions- Nuclear Pharmacies and Radiopharmaceuticals (OAC 4729:5-6-01)

1) Does the TDDD compound or dispense radiopharmaceuticals, radiopharmaceutical preparations, or radioactive drugs?

Yes

2) Does the Nuclear Pharmacy maintain the required licensures?

Yes: TDDD

Yes: Licensed by United States nuclear regulatory commission or the appropriate state nuclear regulatory agency

Observation
Ohio Department of Health RAM license 02500310033, expires 10/1/2026

3) Does the authorized nuclear pharmacist meet the requirements of the rule?

Yes: Has completed 700 hours in structured educational program and obtained written attestation by a preceptor authorized nuclear pharmacist

4) Is the responsible person an authorized nuclear pharmacist?

Yes

5) Institutional Facility: Has an institutional facility with an on-site nuclear pharmacy submitted notification to the board as required by rule?

Not Applicable

2.2) Applicability (OAC 4729:5-6-02)

1) Does the facility prepare, prepare with minor deviation, compound, dispense, or repackage radiopharmaceuticals?

Yes

2.3) Preparation, Compounding, Labeling, Dispensing, Repackaging Radiopharmaceuticals (OAC 4729:5-6-03)

1) Does the TDDD dispense all radiopharmaceuticals pursuant to a patient-specific prescription?

Yes: Radiopharmaceuticals are dispensed pursuant to a patient-specific prescription issued by a licensed health professional authorized to prescribe drugs

Yes: A limited quantity of radiopharmaceuticals are prepared and distributed in anticipation of prescriptions based on routine, regularly observed prescribing patterns

Yes: In the event a patient's name is not available at the time of dispensing, the pharmacy obtains the patient name within 72-hours, and associates it with the prescription dispensing records.

2) Does the TDDD label radiopharmaceutical outer shields with the required information?

Yes: Outer Shields contain the name and telephone number of the pharmacy.

Yes: Outer shields contain the prescription number.

Yes: Outer shields contain the patient's first and last name, or first initial and last name, if available at the time of dispensing.

3) Does the TDDD label the immediate radiopharmaceutical container with the required information?

Yes: Contains the prescription number

Yes: Contains the patient's first and last name, or first initial and last name, if available at the time of dispensing.

4) Does the TDDD ensure all employees comply with all applicable local, state, and federal requirements for proper labeling, environmental controls, integrity, and safety of all products transported?

Yes

5) Does the TDDD ensure all employees comply with applicable local, state, and federal requirements for the disposal of radioactive and/or biohazardous waste?

Yes: The TDDD ensures employees comply with all applicable local, state, and federal requirements for the disposal of biohazardous waste.

6) Do all personnel trained to work with radiopharmaceuticals do so under the supervision of an authorized nuclear pharmacist?

Yes

7) Does the TDDD report medical events to the Ohio Department of Health in accordance with OAC 3701:1-58-101?

Yes

2.4) Record Keeping (OAC 4729:5-6-04)

1) Does the TDDD maintain positive identification records of the authorized nuclear pharmacist conducting the final check of a radiopharmaceutical?

Yes

2) Does the TDDD maintain all records in a readily retrievable, uniform manner for at least 3 years?

Yes: All records are readily retrievable

Yes: All records are uniformly maintained

Yes: All records are maintained for at least 3 years

Yes: All records are kept onsite

2.5.1) Information

2) UPS 825 FAQ Questions 1-18: SCOPE

Observation
SCOPE:
1. What is a Radiopharmaceutical?
A radiopharmaceutical (radiopharmaceutical preparation/radioactive drug) is defined as a finished dosage form that contains a radioactive substance in association with one or more ingredients and that is intended to diagnose, stage a disease, monitor treatment, or provide therapy. A radiopharmaceutical includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance. The term "radiopharmaceutical" and "radioactive drug" are used interchangeably.

Because they contain radioactive materials, radiopharmaceuticals fall under the control of the U.S. Nuclear Regulatory Commission (NRC) or NRC-contracted agreement state agency. Also, because they are prescription drugs, radiopharmaceuticals fall under the control of the U.S. Food and Drug Administration (FDA).

2. Are radiopharmaceuticals classified as NIOSH hazardous drugs because of the radiation hazard?
No. National Institute for Occupational Safety and Health (NIOSH) definition of hazardous drugs excludes radiopharmaceuticals, which are regulated by the Nuclear Regulatory Commission.

3. What is the purpose of ?
The purpose of <825> is to provide uniform minimum standards for the preparation, compounding, dispensing, and repackaging of sterile and non-sterile radiopharmaceuticals for humans and animals that occur as part of state-licensed activities (e.g., the practices of pharmacy and medicine). <825> describes facilities and engineering controls, personnel training and qualifications, and procedural standards for processing radiopharmaceuticals in nuclear pharmacies, nuclear medicine areas in hospitals and clinics, and other healthcare settings that utilize radiopharmaceuticals. For sterile radiopharmaceuticals, these standards balance aseptic handling practices with radiation protection practices to describe appropriate strategies that provide assurance of maintaining patient safety while also ensuring the safety of individuals performing these activities.

4. Why and how was developed?
<825> was developed in response to public comments associated with the 2015 proposed revision of <797>, a white paper in 2016 by the Society of Nuclear Medicine and Molecular Imaging, and a 2017 Stakeholders Workshop held by USP, all of which emphasized the unique characteristics of radiopharmaceuticals which make compliance with <797> difficult or impossible.

<825> was developed by an Expert Panel composed of members from the USP Chemical Medicines 4 Expert Committee (which oversees radioactive drugs), the USP Compounding Expert Committee, FDA, Health Canada, nuclear pharmacists and a nuclear medicine technologist.

The draft of <825> was made available for public comment in July 2018. Public comments were received through November 2018. The final version addressing all the public comments was released June 1, 2019, with an official date of December 1, 2020.

5. To whom and in what settings does apply to?
<825> applies to all individuals who prepare, compound, dispense or repackage radiopharmaceuticals. Applicable individuals consist of authorized nuclear pharmacists (ANPs), and authorized user (AU) physicians, as well as individuals working under their supervision. This includes, but not limited to, student pharmacists, nuclear pharmacy technicians, nuclear medicine technologists and students and physician residents and trainees.

6. How do I know what are requirements versus recommendations in ?
Generally, requirements in a General Chapter are conveyed by use of the term "must." Recommendations are conveyed by use of the terms "should" and "may".

7. What does "official date" mean?
The USP "official date" indicates the date by which affected users are expected to meet the requirements of a particular standard. Ensuring compliance with the requirements of these standards is the responsibility of regulators such as the FDA, states, other government authorities, and accreditation/credentialing organizations. USP has no role in enforcement.

8. When will General Chapter become official?
Please see the Notice of Intent to Revise; December 1, 2020

9. Are the temperatures in expressed in degrees Fahrenheit or Celsius?
Unless otherwise specified, all temperatures in the USP–NF are expressed in degrees centigrade (Celsius) (see also General Notices 8.180 Temperatures).

10. Have there been changes between the proposal in PF44(5) Sep-Oct 2018 and the official version as results of public comments?
Yes. Based on the public comments, changes have been made to <825>. For example, requirements for immediate use preparations have all been presented as new section 3. Immediate Use of Sterile Radiopharmaceuticals. Another example of the change is the time interval for requalification of media fill competency has been increased from 6 months to 12 months. For detailed information on the changes due to public comments, please see the commentary.

11. Is Administration to the patients in the scope of ?
No. <825> explicitly states that it does not cover the "administration of radiopharmaceuticals to patients."

12. Why is needed? Have there been published reports of patient harm from mishandled radiopharmaceuticals?
This chapter describes appropriate standards that provide reasonable assurance of maintaining patient safety while also providing reasonable assurance for the safety of individuals performing these activities.

There have been published reports of patient harm form mishandled radiopharmaceuticals. Patel, et al. reported 16 patients who developed hepatitis C virus infections from a contaminated radiopharmaceutical used in myocardial perfusion studies (Patel PR, et al. Hepatitis C Virus Infections From a Contaminated Radiopharmaceutical Used in Myocardial Perfusion Studies. JAMA. 2006; 296(16):2005-2011.) Moore, et al. reported several patients who developed hepatitis C virus infections from improper handling practices in a nuclear cardiology clinic (Moore ZS, et al. Transmission of Hepatitis C Virus During Myocardial Perfusion Imaging in an Outpatient Clinic. Am J Cardiol. 2011:108;126-132.)

13. How do requirements interface with NRC regulations and RAM license conditions?
As stated in the Introduction, other regulations (e.g., NRC) must be followed in addition to the standards in <825>. In other words, nothing in <825> supersedes NRC regulations and RAM license requirements. For example, in Section 2 it states "as per RAM license requirements, individuals must wear body and as required extremity dosimeters (e.g., a ring worn on a finger) for long term monitoring of personnel radiation exposure. Any extremity dosimeter must be worn underneath the gloves and must not interfere with proper fit of gloves." As another example, Section S.7 states "[a]ll RAM users must comply with the conditions specified in their approved RAM license application and regulations, and RAM license conditions may supersede the requirements for environmental controls described in this section." For sterile radiopharmaceuticals, <825> balances aseptic handling practices with radiation protection practices to describe appropriate strategies that provide assurance of maintaining patient safety while also ensuring the safety of individuals performing these activities.

14. It is unclear whether nuclear medicine departments in hospitals need to follow USP standards because they are not nuclear pharmacies.
The Introduction section of <825> states "This chapter applies to all practice settings where radiopharmaceuticals are prepared, compounded, dispensed, or repackaged. Practice settings consist of state-licensed nuclear pharmacies, federal nuclear pharmacy facilities, and other healthcare facilities, including, but not limited to: nuclear medicine departments in hospitals and clinics, nuclear cardiology clinics (fixed or mobile), and other specialty clinics." <825> goes on to state that "This chapter applies to all individuals who prepare, compound, dispense, or repackage radiopharmaceuticals. Applicable individuals consist of authorized nuclear pharmacists (ANPs) and authorized user (AU) physicians, as well as individuals working under their supervision. This includes, but is not limited to, student pharmacists, nuclear pharmacy technicians, nuclear medicine technologists and students, and physician residents and trainees."

15. I work in a PET drug manufacturing facility that produces a variety of products under ANDAs, INDs, and RDRC approval. In addition, the half-lives of the PET drugs range from 10 minutes to more than 110 minutes. For short-lived products, a single batch is used for a single patient dose. For longer-lived products, a single batch is used for multiple patient doses. For these scenarios, would you please explain the difference between septum punctures that occur under manufacturing and if they matter for purposes of , especially with regard to the Immediate Use provisions of ? It is stated in the chapter that "[T]his chapter does not apply to manufacturing of approved radiopharmaceuticals (e.g., NDA, ANDA, BLA) in FDA-registered manufacturing establishments or Manufacturing of radiopharmaceuticals as investigational agents (e.g., IND, RDRC). In each

of these scenarios, ...the further processing and manipulation of the drug product after release falls within the scope of this chapter."
Punctures made for QC testing are considered pre-manufacturing release and do not apply to <825>.

16. Does a facility that produces radiopharmaceuticals not intended for human or animal use need to follow the provisions of ?
No. The Introduction of <825> states, "This chapter is intended to provide uniform minimum standards for the preparation, compounding, dispensing, and repackaging of sterile and nonsterile radiopharmaceuticals for humans and animals that occur as part of state-licensed activities."

17. What is an Expert Panel vs. Expert Committee?
An Expert Panel is an advisory body formed to provide additional expertise on specific compendial topics and to inform the development of standards by an Expert Committee. An Expert Panel develops recommendations for an Expert Committee; an Expert Panel does not vote on standards.

18. What is a minor deviation and who defines it?
<825> defines preparation with minor deviation as: The act of preparing a conventionally manufactured kit with a conventionally manufactured radionuclide with volume, and/or radioactivity, and/or step-by-step deviations from the manufacturers recommended labeling while ensuring that the final preparation maintains appropriate radiochemical and radionuclidic purity for the entirety of the BUD. Examples of minor deviations include, but are not limited to, altering the amount of activity or volume added to the vial, changes in step-by-step operations (e.g., dilute Tc-99m solution after, rather than before, addition to the vial, use of a venting needle or filter), using alternative devices or equipment (e.g., a heating block rather than a hot water bath), and using alternative radiochemical purity testing methods.

This definition is adapted from published FDA Guidance.

3) USP 825 FAQ Questions 19-20 : Designated Person

Observation

USP 825 | Effective 12/1/2023
USP FAQ for your information. Add as needed to individual inspections.

DESIGNATED PERSON
19. In an outpatient clinic with no associated pharmacy, and therefore no Director of Pharmacy, who is the responsible person for radiopharmaceuticals?
The Authorized User Physician is responsible for radiopharmaceuticals. Section 1. Introduction states: Applicable individuals consist of authorized nuclear pharmacists (ANPs) and authorized user (AU) physicians, as well as individuals working under their supervision.

20. Does the "designated person" have to be someone from the pharmacy department?
No. The Glossary defines the Designated Person as "One or more individuals assigned to be responsible and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repackage radiopharmaceuticals." It is the facility's responsibility to choose a qualified individual to serve as the Designated Person. The chapter does not require a specific number of Designated Persons per site, or the discipline of the person(s) designated.

5) USP 825 Appendix / Abbreviations

Observation
APPENDIX
Abbreviations
ACPH Air changes per hour
ALARA As low as reasonably achievable
ANDA Abbreviated new drug application
ANP Authorized nuclear pharmacist
AU Authorized user
BLA Biologics license application
BSC Biological safety cabinet
BUD Beyond-use date
CETA Controlled Environment Testing Association
cfu Colony-forming unit
CoA Certificate of analysis
DPA Direct processing area
EPA Environmental Protection Agency
FDA Food and Drug Administration
FDCA Food, Drug, and Cosmetic Act
HEPA High-efficiency particulate air
HVAC Heating, ventilation, and air conditioning
IND Investigational new drug
IPA Isopropyl alcohol
ISO International Organization for Standardization
LAFW Laminar airflow workbench
MAA Macroaggregated albumin
MEA Malt extract agar
MFR Master Formulation Record
NDA New drug application
NRC Nuclear Regulatory Commission
PEC Primary engineering control
PET Positron emission tomography
RAM Radioactive material
RDRC Radioactive drug research committee
RH Relative humidity
SDA Sabouraud dextrose agar
SEC Secondary engineering control
SOP Standard operating procedure
SRPA Segregated radiopharmaceutical processing area
TSA Trypticase soy agar

2.5.2) Non-Sterile Radiopharmaceuticals

1) Does the TDDD compound non-sterile radiopharmaceuticals?

No

2.5.3) Sterile Radiopharmaceuticals

1) Does the TDDD compound sterile radiopharmaceuticals?

Yes: The TDDD compounds injectable radiopharmaceuticals (e.g. intravenous, intrathecal, intraperitoneal, subcutaneous, and intradermal).

2) Does the TDDD sterilize compounded radiopharmaceuticals which are made with one or more nonsterile components prior to dispensing?

No.

3) Does the TDDD perform bacterial endotoxin testing on injectable compounded preparations whose components are not certified to be pyrogen free?

Other

Observation
N/A

4) Does the TDDD wipe the vial septum with 70% sterile isopropyl alcohol prior to initial needle puncture?

Yes:

2.5.4) Radiation Safety Considerations

1) Do personnel exposed to radiation minimize handling time to minimize radiation exposure?

Yes: Personnel handling radiopharmaceuticals work in a controlled and safe manner, including multiple hand movements in and out of the ISO 5 PEC during aseptic processes.

2) Do personnel handling radiopharmaceuticals utilize techniques to increase distance between the operator and RAM?

Yes: Personnel handling radiopharmaceuticals use remote handling tools to increase distance between the operator and the RAM

Observation
Work is performed in a hot cell

3) Do personnel handling radiopharmaceuticals utilize shielding materials to limit radiation exposure?

Yes: The TDDD uses lead or tungsten pigs to store completed radiopharmaceutical compounds.

Yes: The TDDD uses lead-lined cabinets and storage containers for storing radioactive waste, isotopes, radiopharmaceuticals and other materials.

Yes: The TDDD uses lead bricks caves or L-Blocks for completing lab work with radioisotopes.

Yes: The TDDD uses syringe shields during dose preparation and administration.

Yes: Radioactive waste storage areas are shielded to minimize exposure rates.

Yes: Lead vial shields are used to house radioactive components.

4) Does the TDDD compound using appropriate radiation contamination control measures?

Yes: Containers are maintained under neutral or negative pressure.

Yes; Clean, disposable absorbent low-lint pads are used to contain radioactive contamination in the ISO 5 PEC

Yes: ISO Class 5 PECs have vertical air flow

5) Do individuals exposed to radiation wear body and extremity dosimeters for long-term monitoring of personnel radiation exposure?

Yes: Body dosimeters are worn underneath gowns.

Yes: Extremity Dosimeters (e.g., ring worn on a finger) are worn underneath gloves.

Yes: Extremity dosimeters do not interfere with the proper fit of gloves.

Yes: Radiation measuring devices are placed inside the ISO 5 PEC in a manner that minimizes disruption of air flow.

Yes: Other necessary equipment (e.g., monitors, barcode scanners, label printers) are placed inside the ISO 5 PEC in a manner that minimizes disruptions of air flow.

2.5.5) Immediate Use of Sterile Radiopharmaceuticals

1) USP 825 FAQ Questions 21-36: Immediate Use

Yes

Observation

USP 825 | Effective 12/1/2023
USP FAQ for your information. Add as needed to individual inspections.

IMMEDIATE USE
21. If the "bulk" Tc-99m pertechnetate vial obtained for contingency usage is used to prepare a radiopharmaceutical for immediate use, can it be saved for additional patient studies?
No, see Section 3, Immediate Use of Sterile Radiopharmaceuticals, which states "All components involved (e.g., Tc-99m sodium pertechnetate syringe or vial, final prepared radiopharmaceutical kit vial, diluent vial) must be discarded within one hour of being punctured or after use for a single patient administration, whichever is first." Therefore, any residual content of all vials utilized must be discarded after 1 hour so it cannot be saved for additional patient studies.

22. Can the area used for radiolabeling food be used for immediate use red cell labeling or other sterile radiopharmaceuticals if cleaned first?
Yes, if the area is used for only one activity throughout the time of handling and then cleaned before it is used for another activity.

Section 3 Immediate Use of Sterile Radiopharmaceuticals states "Area for sterile preparation and/or dispensing must be functionally separate from nonsterile compounding area (e.g., radiolabeling food) during the time of use."

Section 11.1 Compounding Non-sterile Radiopharmaceuticals states "Areas designated for nonsterile compounding must be cleaned and uncluttered and separated from areas designated for sterile radiopharmaceuticals."

Section 10.4 Preparation of Radiolabeled Red Blood Cells for Immediate Use states "A dedicated space for blood handling must be designated through the entirety of the blood radiolabeling process. This area must be free from clutter and not used

for any other radiopharmaceutical preparation or handling until the completion of cleaning and disinfection."

23. Is QC testing required for radiopharmaceuticals prepared under the immediate use provision?
<825> Section 3 is not fully prescriptive on all factors. In Section 8. Assigning BUD, there is discussion of factors that must be considered in determining BUD, including maintenance of radiochemical purity (which may require studies of QC testing over time), but this would rarely be applicable for Immediate Use. In Section 9. Documentation, it requires that records be maintained for "End product radiochemical and other testing, as applicable, results of preparations, preparations with minor deviations, and compounded preparations." For some radiopharmaceutical kits, the package insert preparation instructions require QC testing, but for other radiopharmaceutical kits they do not. Section 10.2 Preparation with Minor Deviations includes a requirement for "appropriate in-house QC testing, designed to validate the radiochemical purity of the product for the entirety of the BUD or is supported by appropriate peer-reviewed publications for the minor deviation utilized." Apart from <825>, QC testing should be performed as a professional standard of practice (for example, see document from SNMMI http://snmmi.files.cms-plus.com/docs/JNMT354p272.pdf; the American College of Radiology https://www.acr.org/-/media/ACR/Files/Practice-Parameters/Radiopharmace...; and the American Pharmacists Association, https://pharmacist.com/sites/default/files/files/Nuclear-Pharmacy-Compo...).

24. Can patient specific doses be prepared for immediate use with contingency Tc-99m sodium pertechnetate?
Yes, <825> allows preparation (including preparation with minor deviations) and/or dispensing that is limited to use for a single patient. Please refer to Section 3. Immediate Use of Sterile Radiopharmaceuticals for more details.

25. For radiopharmaceutical kits prepared under immediate use conditions, must radiochemical purity (RCP) testing be performed?
RCP testing may be fulfilled at the point of care before administration, or through a systematic validation of preparation procedures that ensure RCP. The term Preparation includes not only the process of following the manufacturer's recommendations, but also includes preparations with deviations from the manufacture's recommendations. USP <825> Section 10. on Preparation states: "The individual responsible for preparing the radiopharmaceutical(s) must ensure that the final preparation complies with quality and purity specifications throughout the assigned BUD. This includes, as appropriate for the preparation, radionuclidic purity, radiochemical purity (RCP), chemical purity, and physical and chemical properties" (Italics added for emphasis). The FDA approval process is based on labeling instructions directed to maintain stability throughout the "use by" time. Some radiopharmaceuticals approved before 1990 do not have RCP testing mentioned in their product labeling. The physician or pharmacist is responsible for ensuring that the radiopharmaceutical meets the quality and purity intended by the manufacturer and is responsible for documentation as stated in <825> Section 9. Documentation as applicable to the category of preparation. In these situations, the USP monograph or other equivalent testing method used to ensure the stability throughout the BUD should be sufficiently rigorous to allow statistical confidence in the results.

26. Is the BUD limited to one (1) hour or less for immediate use?
Yes, <825> specifies that the BUD for immediate use is one hour. Please refer to <825> Section 3. Immediate Use of Sterile Radiopharmaceuticals and information in Table 7.

27. For the immediate use category, does the lab coat need to be cleaned daily or does a disposable lab coat need to be used?
In section 4.4, Hand Hygiene and Garbing for Immediate Use Preparation, it states to "...don a clean coat or gown that has not been exposed to a patient of patient care area..." and "a different lab coat must be worn to care for a patient than the coat/gown used for radiopharmaceutical preparation." Each facility should develop policies and procedures on the use and donning of lab coats or gowns consistent with the provisions of this chapter.

28. Can an oral Tc-99m sulfur colloid unit-dose be split into multiple syringes for multiple patients for non-sterile compounding (e.g., radiolabeling food) without an ISO 5 PEC?
Non-sterile compounding does not require an ISO 5 PEC. Section 3 Immediate Use of Sterile Radiopharmaceuticals is only for sterile radiopharmaceuticals.

29. Does manipulating a unit dose by adding or removing volume and changing the needle need to follow the immediate use standards?
Section 3 "Immediate Use of Sterile Radiopharmaceuticals" states "Manipulations for any unit doses (e.g., decreasing the dosage, needle changes) or dispensing for one patient (e.g., withdrawing a dose) is allowed."

30. What considerations must be made when ordering Tc-99m sodium pertechnetate to be used in ambient air, in compliance with the immediate use standards?
When deciding the amount of Tc-99m sodium pertechnetate and whether it should be in a syringe or a vial for emergency usage the following must be considered under Section 3 "Immediate Use of Sterile Radiopharmaceuticals":

Appropriate for preparation (including minor deviations) and/or dispensing that is limited to use for a single patient.
All components involved (e.g., Tc-99m sodium pertechnetate syringe or vial, final prepared radiopharmaceutical kit vial, diluent vial) must be discarded within 1 hour of being punctured or after use for a single patient administration, whichever is first.
Dose pooling (combining doses from two or more syringes to meet one patient's need) may be performed as immediate use.
Any residual activity that remains must be immediately discarded and not utilized for any other patient."
The number of steps or punctures is not limited.

31. If a provider adds lidocaine immediately prior to administration, what standards need to be followed?
In accordance with Section 3 "Immediate Use of Sterile Radiopharmaceuticals, "[w]hile adding a non-radioactive, sterile and commercially manufactured pharmaceutical (e.g., lidocaine) to a unit dose is otherwise considered compounding, it is allowed for immediate use purposes" as long as all of the requirements in Section 3 "Immediate Use of Sterile Radiopharmaceuticals," is adhered to."

32. If a provider is adding lidocaine to 4 syringes containing a radiopharmaceutical for one patient per the immediate use standards, can this be done with 1 vial of lidocaine?
This chapter does not apply to the preparation of non-radioactive drugs, including those used as pharmacologic adjuncts for certain nuclear medicine procedures. Refer to <797> Pharmaceutical Compounding—Sterile Preparations for information on proper handling.

33. What standards need to be followed for food radiolabeling?
The standards for Compounding of Nonsterile Radiopharmaceuticals in Section 11.1 "Compounding Nonsterile Radiopharmaceuticals" need to be followed. These standards are not to be confused with the Sterile Compounding in Section 11.2 "Sterile Compounding" which are different.

34. Is adding Tc-99m sulfur colloid to egg products, dietary supplements, water, or baby formula considered nonsterile compounding?
Section 11.1 "Compounding Nonsterile Radiopharmaceuticals" states "Compounding nonsterile radiopharmaceuticals is the combining, mixing, diluting, pooling, reconstituting or otherwise altering a drug or bulk drug substance other than as provided by the manufacturer's package insert to create a nonsterile radiopharmaceutical." "Requirements for nonsterile oral meal components are limited to common food grade description and are not required to establish identity by validated means."

35. Does splitting a unit dose into multiple doses require an ISO 5 PEC?
Yes. See section 3, which states "Dose splitting (splitting a unit dose for administration to more than one patient) may not be performed as immediate use; if performed, dose splitting must be performed in an ISO class 5 PEC in either an SRPA or in an ISO class 8 or better buffer area."

36. Can a unit-dose of technetium-labeled radiopharmaceutical (e.g., Tc-99m sestamibi, Tc-99m tetrofosmin, sterile filtered Tc-99m sulfur colloid) be divided into multiple syringes without an ISO 5 PEC if to be used for one patient and administered within an hour of the division of the dose?
Section 3 allows for:

Manipulations for any unit doses (e.g., decreasing the dosage, needle changes) or dispensing for one patient (e.g., withdrawing a dose) is allowed.
Must be administered within 1 hour of the first container puncture or exposure of any critical site involved (e.g., syringe tip, needle hub or needle) to ambient air, whichever is first.
All components involved (e.g., ...diluent vial) must be discarded within 1 hour of being punctured or after use for a single patient administration, whichever is first."

2) Does the TDDD prepare immediate use radiopharmaceuticals in an ambient environment that lacks primary and secondary engineering controls?

No.

2.5.6.1) Aseptic Qualifications

1) USP 825 FAQ Questions 37-42: Aseptic Qualifications

Observation

USP 825 | Effective 12/1/2023
USP FAQ for your information. Add as needed to individual inspections.

ASEPTIC QUALIFCATIONS
37. Do students and trainees need to perform gloved fingertip testing and media fill testing prior to preparing sterile radiopharmaceuticals beyond immediate use?
Yes, section 4.1 states: "Personnel must prove competency, as applicable to their job functions, prior to performing radiopharmaceutical aseptic tasks that are beyond immediate use." Specifically, in the media fill section it states: "Media-fill testing is necessary for all personnel who prepare, compound, dispense, and repackage sterile radiopharmaceuticals." Section 4.3 describes the situations when students or visitors do not have to prove competency "Other personnel or visitors (e.g., auditors, regulators, student observers) must comply with garbing SOPs but do not need to prove competency." If the student or trainee will prepare, compound, dispense, or repackage a sterile radiopharmaceutical beyond immediate use (in an ISO class 5 PEC) then they must comply with the aseptic qualifications in section 4 including aseptic technique training, gloved fingertip testing, and media fill testing.

38. Can radiopharmaceuticals be prepared for immediate use if the worker fails the media fill challenge?
Yes, section 3 states: "Does not require personnel to complete the aseptic qualifications as detailed in section 4.1 (e.g., aseptic technique training with documented assessment, media fill challenge, gloved fingertip testing)." so a worker can prepare radiopharmaceuticals for immediate use regardless of the results of their media fill challenge. Nonetheless, some regulatory authorities and accreditors expect documented competency for performance of critical activities, so documentation of training and performance assessment for radiopharmaceutical preparation for immediate use is recommended.

39. Does the media fill proctor need to have specialized or additional training?
Section 4.1 specifies that the media fill challenge will be observed by a "designated person". The designated person is defined as: "One or more individuals assigned to be responsible and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repackage radiopharmaceuticals." The designated person must be appropriately trained in their area of supervision.

40. If a media fill challenge is performed in one facility, does it need to be repeated in every facility the worker works in?
Section 4.1 states "Personnel must prove competency, as applicable to their job functions, prior to performing radiopharmaceutical aseptic tasks that are beyond immediate use. These qualifications may be conducted at a different site if all SOPs are identical for the applicable job function." Media fill testing is one component of competency qualification, <825> does not address if it needs to be repeated in every facility the worker works in. Some regulatory authorities and accreditors may require performance of qualification testing at each facility, so personnel are responsible for knowing and following any such requirements.

41. Certain imaging protocols require radiopharmaceuticals to be re-assayed in the SRPA or buffer room. How does apply?
This is dependent on the location of the dose calibrator. Section 7.6 Cleaning and Disinfecting Items from Patient Care Areastates "Syringes that have been used in a patient care area must not be brought back into the classified area (e.g., buffer or ante-room) or SRPA for re-assaying or disposal unless the syringe in sealed inside an impervious container (e.g., sealed plastic bag) that is disinfected prior to entry into the classified area or SRPA." Users should consult their epidemiology/infection control experts for proper application of standards.

42. Can an individual that has not performed aseptic qualification testing (e.g.,., media fill, gloved fingertip testing) elute from an active (i.e., non-expired, in-use) generator?
Section 4.1 "Aseptic Qualifications" says, "Personnel must prove competency, as applicable to their job functions, prior to performing radiopharmaceutical aseptic tasks that are beyond immediate use." This means that a trainee cannot elute a generator that is beyond immediate use without passing the aseptic qualifications described in Section 4.1.

2) USP 825 FAQ Questions 43-46: Garb

Observation
USP 825 | Effective 12/01/2020
USP FAQ for your information. Add as needed to individual inspections.

GARB
43. Do gloves need to be sterile?
The use of sterile gloves is dependent on the activity beingperformed. When working within an SRPA or buffer room, Section 4.5 requires sterile gloves to be donned, as wearing sterile gloves reduces the bioburden brought into the SRPA or buffer room. When performing immediate use drug preparation, Section 4.4 states "either don sterile gloves or don nonsterile disposable gloves and then disinfect the gloves with sterile 70% IPA". Sterile gloves are not required for immediate use.

44. Should gloves be over or under the gown sleeve?
Gloves should be over the gown sleeve per Section 4.5, which states: "Gloves must completely and snugly cover the ends of the gown cuffs so that skin on the wrists and upper hands is completely enveloped." Users should be reminded that the individual performing the task is considered the highest source of potential particle shedding that can result in microbial contamination.

45. What are considered cosmetics?
Cosmetics are defined in the Federal Food, Drug, and Cosmetic Act as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance." [FD&C Act, § 201(i)] It would not be feasible to list all the different types of cosmetics. Section 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area specifically mentions cosmetics.

46. What hand hygiene and garbing is required in a hot lab without a SRPA and PEC for preparation, dispensing, or repackaging of radiopharmaceuticals? What's the order of garbing? Are sterile gloves required?
Section 3 "Immediate Use of Sterile Radiopharmaceuticals" says "Follow hand hygiene and garbing in 4.4 Hand Hygiene and Garbing for Immediate Use Preparations." Section 4.4 "Hand Hygiene and Garbing for Immediate Use Preparations" states that radiopharmaceuticals may be prepared and dispensed as immediate use, and the precautions related to personal hygiene to be followed, including the requirement to,

Hand hygiene: Wash hands and arms to the wrists with soap and water or use a suitable alcohol-based hand rub with a time based on institution policies to reduce bioburden on the hands.immediately after hand hygiene, don a clean coat/gown that has not been exposed to a patient or patient care area, and either don sterile gloves or don nonsterile disposable gloves and then disinfect the gloves with sterile 70% IPA. [NOTE—A different lab coat must be worn to care for a patient than the coat/gown used for radiopharmaceutical preparation.]

3) The TDDD has standard operating procedures which are authorized by the Nuclear Pharmacist or Physician.

Yes

4) Are individuals with conditions which pose a higher risk of potential contamination of radiopharmaceuticals and the environment with microorganisms excluded from working in sterile processing areas until the condition has resolved?

Yes: Individuals with rashes, sunburn, recent tattoos, oozing sores, conjunctivitis or active respiratory infections report these conditions to their supervisors.

5) Does the TDDD have documentation that personnel successfully completed initial compounding training?

Yes: Personnel have completed aseptic technique training with a documented assessment.

Yes: Compounding personnel have completed a garbing and hand hygiene training as defined in the TDDDs polices and SOPs.

Yes: Compounding personnel have completed PEC cleaning and disinfecting training

Yes: Compounding personnel have completed gloved fingertip sampling.

Yes Compounding personnel have completed media fill testing.

Observation
Employee records not reviewed during inspection. Pharmacy to ensure proper completion and documentation are in place.

6) Does the TDDD have initial gloved fingertip and thumb sampling results for compounding personnel?

Yes: Gloved finger tip and thumb sampling was performed initially on both hands.
Yes: Gloved fingertip and thumb sampling was performed immediately after hand hygiene and garbing.
Yes: Initial gloved fingertip and thumb sampling had zero colony-forming units (cfu).
Yes: Gloved fingertip sampling was performed with touch plates or other devices that contain a general microbial growth agar.
Yes: Gloves were not disinfected immediately prior to touching the sampling device.
Yes: A separate sampling device was used for each hand.
Yes: The gloved fingertip and thumb were collected by rolling finger pads and thumbs over the agar surface.
Yes: Plates were incubated at 30-35 C for not less than 48 hours, and then at 20-25 C for no less than 5 additional days.

Observation
Employee records not reviewed during inspection. Pharmacy to ensure proper completion and documentation are in place.

Paddles slides are permitted. Agar contains trypticase soy agar (TSA) soybean0casein digest media supplemented with neutralizing additives (e.g., lecithin and polysorbate 80). to support bacterial and fungal growth.

7) Does the TDDD conduct a media fill test reflective of the actual manipulations carried out under the most challenging and stressful conditions encountered in the worker's duties?

Yes: Media fill tests are documented as defined in the TDDDs SOPs.
Yes: Media fill tests are performed at the end of the work session in the PEC.
Yes: Media fill tests are performed with a commercial source of soybean-casein digest medium.
Yes: Sterile to sterile processing activities start with sterile media.
Yes: The CoA includes documentation of growth promotion testing for each lot of media used.
Yes: Final containers are incubated for 7 days at 20-25C followed by 7 days at 30-35C.
Yes: Media fill failures and corrective action is documented to maintain a long-term assessment of personnel competency.

Observation
Employee records not reviewed during inspection. Pharmacy to ensure proper completion and documentation are in place.

Failure = visual manifestations of growth in the medium on or before 14-days.

8) Does medial fill documentation contain the required information?

Yes: Name of the person evaluated.
Yes: date/time of evaluation.
Yes: Media and components used , including manufacturer.
Yes: Expiration date and lot number of media fill components.
Yes: Starting temperature for each interval of incubation
Yes: Dates of incubation.
Yes: Incubation results.

Observation
Employee records not reviewed during inspection. Pharmacy to ensure proper completion and documentation are in place.

2.5.6.2) Reevaluation, Retraining, and Requalification

1) Does the TDDD require personnel who fail aseptic qualifications to pass reevaluations in deficient areas before resuming sterile compounding?

Yes: All failures, retraining, and reevaluations are documented.

Observation
Did not observe any failures; RP discussed the pharmacy's process.

2) Are personnel visually observed while performing hand hygiene, garbing and aseptic technique procedures initially, and at least once every 12-months?

Yes: Personnel are visually observed during initial qualifications for hand hygiene, garbing, and aseptic technique.

Yes: Personnel are visually observed at least once every 12-months for hand hygiene, garbing, and aseptic technique requalification.

Yes: Gloved fingertip sampling is performed 3 times initially.

Yes: Gloved fingertip testing is performed every 12 months in conjunction with media fill testing for requalification.

Yes: There is an initial media fill qualification.

Yes: After initial qualification a media-fill test is completed for all personnel engaged in sterile radiopharmaceutical processing at least every 12 months (in conjunction with gloved fingertip and thumb sampling).

Yes: There is an initial training for cleaning and disinfecting.

Yes: Personnel are retrained in the cleaning and disinfecting of sterile processing areas every 12-months.

Yes: Personnel who have not performed radiopharmaceutical processing in more than 6-months are requalified in all core competencies before resuming duties.

Yes: Personnel are retrained in any core competencies if there are changes in the SOP.

2.5.6.3) Ancillary Personnel

1) Does the TDDD require ancillary personnel who are authorized to be in the sterile processing area, but who do not handle sterile preparations complete training and testing?

Other.

Observation
Ancillary personnel are not permitted in the sterile processing area.

2.5.6.4) Hand Hygiene and Garbing for Immediate Use Preparations

1) Does the TDDD perform hand hygiene for immediate use radiopharmaceutical preparation?

Yes: Compounders wash hands from the arms to the wrists with soap and water, or use a suitable alcohol based hand rub with a time based on policies to reduce bioburden on the hands.

Yes: Immediately after hand washing, a clean gown is donned that has not been exposed to patients or patient care areas.

Yes: Immediately after hand washing and gowning, sterile or non-sterile disposable gloves are donned.

Yes: After donning disposable gloves they are disinfected with 70% IPA.

2.5.6.5) Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Areas

1) Does the TDDD follow hand hygiene precautions when repackaging, dispensing, preparing, preparing with minor deviations, or compounding sterile radiopharmaceuticals in an ISO 5 PEC?

Yes: Compounding personnel remove all outer garments, cosmetics, hand, wrist, and exposed jewelry, nail products, ear bud/headphone's prior to entering the SRPA or buffer area.

Yes: Electronic devices that are not necessary for compounding or other required tasks are not permitted in the SRPA or buffer area.

Yes: Before entering the SRPA or buffer area visible debris is removed from underneath fingernails using a disposable nail cleaner.

Yes: Personnel wash hands and arms up to the elbows with soap and water for at least 30-seconds and dry hands using low-lint towels.

Yes: Personnel don shoe covers, head/hair/facial hair covers, and face masks in an order that eliminates the greatest risk of contamination.

Yes: Personnel perform hand antisepsis cleaning using a suitable alcohol-based hand rub.

Yes: Personnel don a low-lint gown that fits snugly around the wrists and enclosed at the neck.

Yes: Personnel aseptically don sterile, powder-free gloves that completely and snugly cover the ends of the gown cuffs. Skin on the wrists and upper hands is completely covered.

Yes: Personnel periodically apply sterile 70% IPA to gloves.

Yes: Personnel routinely inspect gloves for holes, punctures, radioactive contamination, or tears.

Yes: if a glove defect is detected, personnel immediately remove gloves, repeat aseptic hand cleansing using an alcohol based hand rub and don new sterile gloves.

Yes: Personnel avoid touch contamination of container septa, needles, syringes, needle hubs, and other critical sites.

Observation

(Hand washing may be performed after donning shoe covers, head/hair covers, and facemasks).

(Disposable gowns are preferred. If reusable gowns are used, a clean gown must be donned daily.)

2) Do compounders dispose of shoe covers, head/hair covers, face masks, and gloves when exiting the buffer area or SRPA?

Yes:

3) Do personnel re-use gowns during the same shift if the gown is maintained in the classified area?

Yes: Gowns are maintained in a classified area or in (or immediately outside of) the SRPA and reused during the same shift.

2.5.7.1.1) Types of Secondary Engineering Controls

1) USP 825 FAQ Questions 47-53: Facility

Observation
USP 825 | Effective 12/1/2023
USP FAQ for your information. Add as needed to individual inspections.

FACILITY
47. Is a fume hood or vent hood the same thing as an ISO 5 PEC?
As stated in the glossary a PEC is: "A device or zone that provides an ISO Class 5 air quality environment for sterile processing." Table 1 specifies the particles in ISO Class 5 air quality to be less than 3520 particles/m3 for the number of particles ≥0.5 µm measured under dynamic operating conditions through the use of high efficiency particle (HEPA) filter. In contrast, a fume hood does not contain a HEPA filter and exhausts volatile chemicals or radioactivity out of the room to protect the operator but does not protect the sterile radiopharmaceutical from bacterial or fungal contamination. Sometimes a fume hood is required by a RAM license, but because it does not have a HEPA filter, it cannot be considered a PEC for sterile drug preparation.

48. Can a fume hood be retrofitted into an ISO 5 PEC?
No, because the standard equipment to qualify for an ISO 5 PEC is specialized and cannot be added to an established fume hood setup.

49. Is a biosafety cabinet required for xenon?
A biological safety cabinet (BSC) is NOT appropriate for Xenon gas – rather, radioactive gases should be stored and handled in a chemical fume hood or as otherwise described in the facilities specific Radioactive Material (RAM) license.

50. Does a Containment Segregated Compounding Area need to comply with and include a biosafety cabinet?
A Containment Segregated Compounding Area (C-SCA) is a facility defined in USP <800> Hazardous Drugs — Handing in Healthcare Settings and is not the facility design allowed in <825>.

51. Should the "Hot Lab" be negative pressure to the Segregated Radiopharmaceutical Processing Area and the corridor?
<825> does not specify pressure differentials for the "hot lab", Segregated Radiopharmaceutical Processing Area (SRPA), or other non-classified areas; pressure differentials must comply with conditions described in the facility's Radioactive Material License.

52. Is it permissible to prepare kits utilizing Ge-68/Ga-68 generators outside an ISO Class 5 environment?
As noted in Table 7, a secondary engineering control environment with an ISO 8 total airborne particle count is appropriate for eluting Ge-68/Ga-68 generators. Any Ge-68/Ga-68 generator eluent container or tubing assembly/connections should take place within an ISO Class 5 PEC. Additional manipulations of the product, including but not limited to withdrawing a quality control sample, buffering the preparation, etc., must be performed in an ISO 5 environment.

53. Can two vials of Y-90 microspheres be prepared from one manufactured vial to treat separate areas of the liver for one patient using the immediate use standards?
Section 3 "Immediate Use of Sterile Radiopharmaceuticals" says "The preparation and dispensing of sterile radiopharmaceuticals in a patient care setting may be handled as an immediate use practice. The information below describes the appropriate handling requirements for immediate use sterile radiopharmaceuticals in an ambient environment that lacks primary and secondary engineering controls (SEC) when intended for a single patient. Strict aseptic technique and limited beyond-use date (BUD) must be adhered to given the lack of engineering controls.

- Appropriate for preparation (including minor deviations) and/or dispensing that is limited to use for a single patient (emphasis added).
- Must be administered within 1 hour (emphasis added) of the first container puncture or exposure of any critical site involved (e.g., syringe tip, needle hub or needle) to ambient air, whichever is first.
- All components involved (e.g., Tc-99m sodium pertechnetate syringe or vial, final prepared radiopharmaceutical kit vial, diluent vial) must be discarded within 1 hour of being punctured or after use for a single patient (emphasis added) administration, whichever is first.

2) USP 825 FAQ Questions 54-57: SRPA

Observation

USP 825 | Effective 12/1/2023
USP FAQ for your information. Add as needed to individual inspections.

SRPA
54. Can an SRPA be inside a hot lab?
Yes, if the SRPA meets the requirements specified in Section 5 Facilities and Engineering Controls for an SRPA it can be a subsection of the hot lab. Per the definition in the glossary, a hot lab is "Unclassified radiopharmaceutical processing area located within a hospital or clinical site that is only appropriate for immediate use radiopharmaceuticals if there is not an ISO 5 PEC within SRPA located within the area."

55. Should the Segregated Radiopharmaceutical Processing Area be positive pressure to comply with USP 825, and include a Biosafety cabinet or Glove box?
A Segregated Radiopharmaceutical Processing Area (SRPA) does not specify pressure differentials; these must comply with conditions described in the facility's Radioactive Material License. A SRPA must include an ISO 5 PEC (e.g., vertical laminar airflow workbench or Class II Biological Safety Cabinet) for radiopharmaceutical processing activities. A glove box, a negative pressure radiological containment unit does not contain a HEPA filter, and therefore is not an acceptable environment for the production of radiopharmaceuticals.

56. Is an anteroom or ante area required for a Segregated Radiopharmaceutical Processing Area?
No, an ante-room is not required for a Segregated Radiopharmaceutical Processing Area (SRPA). An ante-room is only required for entry into a buffer area (sometimes referred to as a cleanroom).

57. What are the minimum requirements to elute Tc-99m/Mo-99 generators?
Section 5.1 "Facility Design and Environmental Controls" says "If the SRPA meets ISO Class 8 total airborne particle count specifications, it can also be used for storage and elution of non-direct infusion radionuclide generators (e.g., Tc-99m)."

Section 5.3 "Water Sources" says "In a facility with an SRPA design, the sink must be accessible but located at least 1 m from the PEC and generators, if present." Table 7 says that the BUD for generators eluted in an SRPA with ISO Class 8 total airborne particle counts may not be longer than 12 hours.

3) Does the facility have documentation that the work environment is maintained under appropriate conditions?

Yes: Classified areas and the SRPA are continuously maintained at a temperature of 25C (77F)

Yes: Relative humidity is continuously maintained below 60%.

Yes: The temperature and humidity are monitored each day, either manually or by a continuous recording device.

Yes: Temperature and humidity readings are documented at least once daily or stored in the continuous recording device and are retrievable.

Yes: Temperature and humidity readings are reviewed as described in the facility SOPs

Yes: Free standing humidifiers/dehumidifiers or air conditioners are not used within the classified area or the SRPA.

Yes: Temperature and humidity monitoring devices are verified for accuracy at least every 12-months or as required by the manufacturer.

Yes: The designated person ensures each area related to sterile radiopharmaceutical processes meets the classified air quality standard.

Yes: The designated person ensures the ISO Class 5 PECs are located, operated, maintained, monitored, and certified to have appropriate air quality.

Observation
Temperature/humidity sensors are replaced annually.
Temperature/humidity are maintained electronically.

4) Is the PEC located in a SEC?

Yes: The PEC is located in an ISO-classified buffer room with an anteroom.

Yes: The ISO classified anteroom and buffer area are separated from the surrounding unclassified areas of the facility with fixed walls and doors.

Yes: Air supplied to the classified areas is introduced through HEPA filters located in the ceiling.

Yes: Smoke studies are repeated whenever a change to the placement of the PEC is made.

Yes: Classified areas are equipped with pressure-differential monitoring systems.

Yes: The anteroom has a line of demarcation separating the clean side from the less clean side.

Yes: The anteroom is entered through the less clean side and the clean side is located closest to the buffer area.

Yes: Required garb is worn prior to crossing the line of demarcation (see section 4.6).

5) Is the PEC located in an unclassified area without an anteroom or buffer area?

No:

2.5.7.1.2) The Radiopharmaceutical Processing Environment

1) Is the PEC certified to meet ISO Class 5 or better conditions, and does it minimize microbial contamination during processing under dynamic conditions?

Yes: The PEC is certified to meet ISO Class 5 or better conditions.

Yes: The PEC is designed to minimize microbial contamination during processing of radiopharmaceuticals under dynamic conditions.

2) Is the PEC airflow unidirectional?

Yes:

3) Is HEPA filtered air supplied in the direct processing area at a velocity sufficient to sweep particles away from aseptic processing areas?

Yes

4) Do smoke studies conducted in the critical area demonstrate unidirectional airflow and sweeping action under dynamic conditions?

Yes:

2.5.7.1.3) Types of PECs and Placement

1) Does PEC placement allow for cleaning around the PEC?

Yes:

3) Does the Class II BSC provide an ISO Class 5 or better environment for preparing sterile radiopharmaceuticals?

Yes:

4) Is the PEC located out of traffic patterns and away from area air currents that could disrupt the intended airflow patterns inside the PEC?

Yes:

5) Is the ISO Class 5 PEC placed in an SRPA used only to prepare, prepare with minor deviations, or repackage sterile radiopharmaceuticals?

Other:

Observation
N/A

6) Are sterile radiopharmaceuticals compounded in a PEC located within an ISO Class 7 or better buffer area within an ISO Class 8 or better ante-room?

Yes:

Yes: Dynamic airflow smoke pattern tests are performed initially.

Yes: Dynamic airflow smoke pattern tests are performed every 6 months to ensure the PEC is properly placed.

Yes: Staff are trained to utilize the unidirectional airflow to maintain first air as much as possible given the limitations added from the radiation shielding in the DPA

2.5.7.1.4) Air-Exchange Requirements

2) Are a minimum of 30 total HEPA-filtered ACPH supplied to ISO Class 7 areas?

Yes: The total HEPA filtered air exchange rate maintains ISO Class 7 under dynamic operating conditions.

Yes: At least 15 ACPH of the total air change rate in a room comes from the HVAC through HEPA filters located in the ceiling.

Yes: The HEPA filtered air from the PEC when added to the HVAC supplied HEPA-filtered air increases the total HEPA-filtered ACPH to at least 30 ACPH.

Observation
Buffer room ACPH = 72

3) Is a minimum of 20 ACPH of HEPA-filtered air supplied to the ISO Class 8 areas?

Yes: The total HEPA-filtered air change rate maintains ISO Class 8 under dynamic operating conditions.

Yes: At least 15 ACPH of the total air change rate in a room comes from the HVAC through HEPA filters located in the ceiling.

Yes: The total ACPH is documented on certification reports.

Observation
Ante room ACPH = 21

2.5.7.2.1) Classified Areas

1) Are surfaces of ceilings, walls, floors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in classified areas smooth, impervious, free from cracks, crevices, and non-shedding?

Yes:

2) Do surfaces of ceilings, walls, floors, door frames, fixtures, shelving, work surfaces, counters and cabinets in classified areas maintain easily cleanable conditions?

Yes: Surfaces are resistant to damage by cleaning agents, disinfectants, and tools used to clean.

Yes: Junctures between the ceiling and walls and between the walls and the floor are sealed to eliminate cracks and crevices where dirt can accumulate.

Yes: Walls are constructed of or covered with durable material and the integrity of the surface is maintained.

Yes: Floors include coving to the side wall or the juncture between the floor and wall is caulked.

Yes: Classified areas minimize dust-collecting overhangs.

Yes: Overhangs or ledges which are present are easily cleanable.

Observation

(e.g., epoxy-painted walls or heavy gauge polymer)

(e.g., utility pipes or windowsills)

2.5.7.2.2) SRPA

1) Is the SRPA and all surfaces within the SRPA clean, uncluttered, and dedicated to sterile radiopharmaceutical processing activities?

Other:

Observation
N/A

2.5.7.3) Water Sources

1) Do activities such as hand hygiene and garbing allow the PEC to function as designed?

Yes: Sinks enable hands-free use and have a closed system of soap.

Yes: The sink used for hand hygiene is located outside of the ante-room in a clean space to minimize the risk of brining contaminants into the ante-room.

Yes: The buffer area does not contained plumbed water sources.

Yes: The anteroom does not contain floor drains.

Observation
(i.e., non-refillable soap)

2.5.7.4) Placement and Movement of Materials

1) Are materials used in the classified area or SRPA appropriately transported and stored?

Yes: Only furniture, equipment, and other materials necessary for operations are permitted in the classified area or SRPA.

Yes: All furniture, equipment and other materials located in the classified area or SRPA are low-shedding and are easily cleaned and disinfected.

Yes: Furniture, equipment and other materials do not adversely impact environmental air quality, and promote effective cleaning and disinfecting.

Yes: No shipping cartons or corrugated or uncoated cardboard are allowed in the classified area or SRPA.

Yes: Carts used to transport components or equipment are constructed from non-porous materials with cleanable casters and wheels.

Yes: All items are wiped with low-lint wipers and appropriate disinfectant by gloved personnel prior to entering the clean side of the anteroom, pass-through, or into an SRPA or ISO5 PEC.

Yes: procedures prevent excessive radiation exposure and follow ALARA safety principles.

Observation

(e.g., Staff do not wipe unshielded sources of radioactive materials)

2.5.7.5) Classified Areas

1) Are activities and tasks carried out within the buffer area limited to only those necessary?

Yes: Food, drinks, and materials exposed in patient care and treatment areas does not enter anterooms or buffer areas.

2.5.7.6) Remote Aseptic Processing Involving a Hot-Cell

2) Does the facility utilize a hot cell for aseptic processing?

Yes

3) Does the facility require proper hand hygiene and garbing when using a hot cell?

Yes: The hot-cell is located in an ISO-classified space and personnel garb according to the requirements of 12.4.6, hand hygiene and garbing.

Yes: Personnel garb in relation to the contamination risk when hand and arm incursions into the interior of the hot-cell are necessary to stage required materials and supplies.

4) Are dynamic airflow smoke pattern tests conducted for PECs located in hot cells, and do staff garb accordingly?

Yes: Dynamic airflow smoke pattern tests show the staging of supplies and materials in teh demarcated PEC do not allow the influx o unclassified air into the PEC.

Yes: Personnel garb in accordance with hand hygiene requirements (see 12.4.6) for buffer areas and SRPA areas for all incursions into the hot-cell.

5) Is the hot-cell an integrated HEPA filtration system with a clear demarcated area that is a PEC?

Yes: Dynamic airflow smoke pattern tests show the staging of supplies and materials into the demarcated PEC do not allow the influx of less than ISO Class 5 quality air into the PEC.

Yes: other hot-cell/PEC configurations and technologies ensure upon each certification thta the staging of materials and supplies does not allow for the intrusion of less than ISO 5 class air into the designated ISO Class 5 space.

2.5.7.7) Environmental Controls

2) What type of ISO compounding area does the facility have?

Yes: The facility has an ISO Class 7 buffer area with a vertical flow ISO Class 5 PEC with an adjacent ISO Class 8 or better anteroom.

Yes: The facility has a hot-cell.

3) Do pass-through enclosures provide a reasonable balance between maintenance of air quality and other worker safety concerns?

Yes: There is a mechanical system or SOP in place that ensures both doors cannot be open at the same time.

4) Are pressure differentials in place to minimize the potential for microbial contamination in sterile drug preparation areas?

Yes: Positive pressure environments have a minimum differential pressure of 0.02-inch water column between each ISO-classified area.

Yes: The pressure differential between the anteroom and the unclassified area is not less than a positive 0.02-inch water column.

Yes: The buffer area is positive pressure compared to the anteroom.

Yes: The anteroom is positive pressure compared to unclassified portions of the restricted area.

Observation
Pressure from buffer to ante room: 0.22
Pressure from ante to unclass: 0.08

5) ESTABLISHING AND MAINTAINING PRESSRUE DIFFERENTIALS: Is a continuous pressure differential monitoring system in place?

Yes: There is a pressure differential monitoring system that continuously monitors the pressure between the anterooms and buffer areas.

Yes: There is a pressure differential monitoring system that continuously monitors pressures between the anteroom and the general environment outside the classified area(s).

Yes: The results from the pressure monitoring system are reviewed and documented at least daily on days the area is used.

Yes: All pressure monitoring devices are tested for accuracy and required performance at least every 6 months.

6) AMBIENT ATMOSPHERE FOR IMMEDIATE USE PREPARATIONS: Does the facility meet the requirements for ambient atmosphere environments?

Yes: Designated areas for medication preparation are clean and free from clutter.

Yes: There is a low-traffic area for pharmaceutical processing.

7) SRPA WITH VERTICAL FLOW ISO CLASS 5 PEC FOR RADIOPHARMACEUTICAL PREPARATIONS: Does the SRPA with vertical ISO Class 5 PECs meet the following requirements?

Other:

Observation
N/A

8) CERTIFICATION OF PECS AND ENVIRONMENT IN WHICH THE PEC IS LOCATED: Are classified areas certified initially and every 6 months as required?

Yes: Certification of classified areas and PECs are performed initially.

Yes: Recertification of classified areas and PECs is performed at least every 6 months.

Yes: Certifications and recertification is completed using the current CETA guide for sterile compounding facilities or an equivalent guide?

Yes: Certification includes airflow testing to determine acceptable air velocity, the air exchange rate, and the area pressure cascade to ensure air consistently flows from most to least clean during dynamic operating conditions.

Yes: HEPA filters are leak tested after instillation and as part of recertification.

Yes: Total particle counts are conducted under dynamic operating conditions using calibrated electronic equipment.

Yes: Smoke visualization studies are performed under simulated or dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the preparation.

Observation
Most recent recertification was performed May 19, 2025 by ENV Services.

9) DAILY MONITORING OF THE ENVIRONMENT: Are temperatures and pressure differentials monitored daily?

Yes: Relative humidity is kept at 60% or lower.

Yes: Temperature and relative humidity continuous readings are confirmed daily to have remained within acceptable range.

Yes: Excursions are documented and if applicable, appropriate corrective actions were taken.

Yes: Temperature monitoring devices are verified for accuracy every 12-months or as required by the manufacturer.

Yes: Pressure Differentials are monitored each day preparations are made either manually or by a continuous recording device.

2.5.8.1) General Monitoring Requirements

1) Has the facility implemented a written air and surface monitoring procedure for all sterile radiopharmaceutical classified areas?

Yes: The facility has written air and surface monitoring procedures for all sterile radiopharmaceutical classified areas.

Yes: Air and surface monitoring results are documented.

Yes: Air and surface corrective actions are documented.

Yes: Records are readily retrievable and available for 3 years.

2) Does the air and surface monitoring program include viable impact volumetric airborne particulate sampling and surface sampling?

Yes:

3) Does the facility regularly review sampling data to detect trends such as elevated levels of microbial burden, elevated levels of nonviable particulates, or other environmental changes?

Yes: results are collected over a period of time to identify trends or determine if significant changes have occurred.

Yes: Results are reviewed in conjunction with personnel data to assess the state of control and to identify potential risks of contamination.

Yes: Prompt corrective action is taken for any adverse findings to maintain environmental quality and control.

Yes: Data is reviewed following corrective actions to confirm the actions taken are effective.

4) Are air and surface samples conducted during actual or simulated dynamic operating conditions?

Yes: Sampling is carried out at the conclusion of sterile radiopharmaceutical processing, but prior to cleaning and disinfecting the surface area.

Yes: Simulated tasks that are reflective of the routine aseptic activities are performed.

Yes: Sampling is conducted in conjunction with the certification of new facilities and equipment.

Yes: Sampling is conducted after any modification of facilities or equipment.

Yes: Sampling is conducted in response to any identified problems (e.g., positive growth in sterility tests).

Yes: Sampling is conducted in response to any identified trends (e.g., repeated positive gloved fingertip/media fill failures.)

Yes: Sampling is conducted in response to changes that could impact the controlled area environments. (e.g., significant change in cleaning agents)

5) Are air and surface samples conducted under dynamic or simulated dynamic operating conditions in all PECs and classified areas?

Yes: Sampling occurs during actual sterile processing and is designed to minimize the chance that sampling will contribute to the contamination of the sterile product or environment.

Yes: The air and surface monitoring program is clearly described in the facility SOPs.

Yes: SOPs include sampling frequencies, sampling size, sampling time of day in relation to activities in the classified area, and action levels which trigger corrective action.

Yes: Locations of sampling are selected based on their relationship to the activities performed.

Yes: Samples are obtained from locations that pose the highest possible contamination risk, and are likely to be representative of the conditions throughout the area.

Yes: The facility evaluates results over a period of time to identify trends and to determine if significant changes have occurred, even if the results fall within the prescribed limits.

Yes: Personnel operating sampling equipment are trained in its proper operation

Yes: Air sampling devices are serviced and calibrated according to the manufacturer.

2.5.8.2.1) Viable Air Sampling: Timing and Locations

1) Is volumetric active air sampling of all classified areas conducted using an impaction device under dynamic operating conditions or simulated operating conditions at least every 6 months?

Yes: Viable air sampling follows the device manufacturer directions.

Yes: Sampling tests at least 1 cubic meter of 1000 liters of air from each location sampled.

Yes: At the end of the sampling, the media plates are covered.

Yes: Media plates are inverted and incubated at 30-35C for no less than 48 hours.

Yes: Incubated plates are examined for growth and the total number of discrete colonies of microorganisms are recorded on each plate as cfu/m3 of air on an environmental sampling form which includes the sample location and date.

Yes: Inverted media is then incubated at 20-15C for no less than 5 additional days.

Yes: After the second incubation plates are examined for growth and the total number of discrete colonies are recorded as cfu/m3 on an environmental sampling form which includes the sample location and date.

2) Does the facility use an alternative means to shorten the overall incubation period?

No:

3) Does the facility use proper growth medium?

Yes: A general microbial growth medium that supports the growth of bacteria and fungi is used (e.g., TSA)

Yes: CoA(s) from the manufacturer verify the medium meets the expected growth promotion, pH, and sterilization requirements.

4) Are incubators used for viable sampling correctly monitored and placed?

Yes: Samples are incubated in a temperature monitored incubator.

Yes: The incubator measuring device is calibrated.

Yes: The incubator temperature is monitored during incubation, either manually, or by a continuous recording device.

Yes: Incubator temperatures are reviewed and documented.

Yes: Incubators used for microbiological testing are placed in locations outside of any classified area or SRPA.

Yes: Incubators are kept away from areas where compounding or sterile processing activities are carried out.

Yes: All sampling is performed by trained individuals.

Observation
Incubator temperatures are verified daily, even if not being actively used.

2.5.8.2.2) Data Evaluation and Action Levels

1) Does the facility evaluate cfu counts against action levels?

Yes: The facility evaluates cfu counts against the action levels per ISO class.

Yes: The facility evaluates cfu counts to identify trends.

Yes: If two pieces of media were collected at a single location recovered growth is documented and action levels are applied individually.

Yes: If levels exceed allowable levels for the ISO classification the cause is investigated and corrective action is taken.

Yes: Corrective action plans depend on the cfu count and microorganism recovered.

Yes: The extend of investigation is consistent with the deviation and includes an evaluation of trends.

Yes: Corrective action plans are documented.

Yes: if viable air sampling results exceed ISO action levels an attempt is made to identify the organism recovered to the genus level.

Observation
ISO 5 > 1 cfu, ISO 7 > 10 cfu, ISO 8 >100 cfu

2.5.8.3.1) Surface Sampling: Timing and Locations

1) Are surface samples in all classified areas and all PECs conducted at least monthly?

Yes. Surface sampling is conducted in all classified areas monthly.

Yes. Surface sampling is conducted in all PECs monthly.

Yes. The direct processing area of the PEC is sampled.

Yes. Equipment permanently contained in the PEC is sampled.

Yes. Staging or work surfaces in classified areas near the PEC are sampled.

Yes. Frequently touched surfaces in classified areas and pass-through enclosures for all classified areas are evaluated to determine the locations that pose the greatest risk of harboring microbial contamination.

2) Is surface sampling performed at the end of the radiopharmaceutical aseptic activities or shift, but before the area has been cleaned and disinfected.

Yes. Samples are performed at the end of the radiopharmaceutical aseptic activities prior to cleaning and disinfection.

Yes. Exposure and contamination prevention measures are taken prior to and while collecting samples.

Yes. When assessment show a risk for exposure is not in conformance with ALARA safety standards, measures are taken to eliminate the risk.

2.5.8.3.2) Sampling Procedures

1) Does the facility utilize surface sampling devices which contain microbial growth media?

Yes: Plates, paddles, or slides are used for sampling flat surfaces.

Yes: CoAs from the manufacturer verify the media meets the expected growth promotion, pH, and sterilization requirements.

Yes: Surface sampling devices contain general microbial growth media (e.g., TSA) supplemented with neutralizing agents (e.g., lecithin and polysorbate 80).

Yes: Contact plates have raised convex surfaces.

Yes: After sampling the area is thoroughly cleaned and disinfected.

2) Does the facility follow proper procedures for surface sampling on flat surfaces?

Yes: The sampling device is firmly pressed using a rolling motion onto the surface to be sampled.

Yes: The plate is covered and inverted.

Yes: The plate is incubated for 48 hours at 30-35 C.

Yes: The total number of discrete colonies of microorganisms on each sample is recorded.

Yes: Results include the sample date, location and number of cfu/sample identified.

Yes: The place is incubated an additional 5 days at 20-25 C.

Yes: Results record the total number of discrete colonies of microorganisms/sample (cfu/sample), and includes the date and sample location

3) Does the facility collect two samples for each sample location to shorten the overall incubation period?

No

2.5.8.3.3) Data Evaluation and Action Levels

1) Does the facility evaluate cfu counts against the action levels and examine counts in relation to previous data to identify adverse results or trends?

Yes:

2) Is the extent of the investigation consistent with the deviation?

Yes; Corrective action plans are documented.

Yes: An attempt is made to identify microorganisms to the genus level if surface sampling action levels are exceeded.

Yes: The facility utilizes a qualified individual (e.g., microbiologist or industrial hygienist) to assist with corrective action plans.

2.5.9.1) General Cleaning and Disinfecting

3) Do SOPs specify times the PEC should be shielded to reduce radioactivity prior to cleaning?

Yes: SOPs specify trigger levels for safe cleaning.

Yes: The PEC is checked for radioactive contamination prior to cleaning and disinfecting.

4) Do facility SOPs describe appropriate cleaning procedures?

Yes: Cleaning personnel are trained.

Yes: Cleaning personnel are appropriately garbed.

Yes: Cleaning is performed from the most to least clean areas.

Yes: SOPs describe the frequency and methods of cleaning.

Yes: SOPs describe the sporicidal agent used in accordance with manufacturer instructions.

Yes: The manufacturer's data on the minimum contact time is followed for cleaning and disinfecting and sporicidal agents used.

Yes: When sterile 70% IPA is used, it is allowed to dry.

Yes: There is documentation of cleaning according to facility guidelines.

Observation
Sporicidal agent: Peridox
Cleaning log is completed daily when compounding occurs

5) Does the facility follow the minimum frequency for cleaning the PEC and equipment inside the PEC?

Yes: Prior to performing sterile processing each day, the walls, bars, torso shield, and any exposed surfaces of equipment inside the PEC are cleaned.

Yes: Prior to performing sterile processing each day, during cleaning, radioactive contamination is shielded with appropriate temporary material that is low-lint or has low shedding properties.

Yes: Following cleaning each day, exposed surfaces of equipment are disinfected.

Yes: Prior to daily disinfecting low-lint absorbent pads are removed and the PEC is surveyed for radioactive contamination.

Yes: Following daily disinfecting or spill cleanup, new low-lint absorbent pads are placed in the PEC.

Yes: Sporicidal agents are applied monthly to the PEC.

6) Does the facility follow the minimum frequency for cleaning surfaces of sinks, hot cells, worksurfaces outside the PEC, and floors?

Yes: Sinks, hot cells, work surfaces outside the PEC, and floors are cleaned daily.

Yes: Sinks, hot cells, work surfaces outside the PEC, and floors are disinfected daily.

Yes: A sporicidal agent is applied to sinks, hot cells, work surfaces outside the PEC, and floors monthly.

7) Does the facility follow the minimum frequency for cleaning ceilings, walls, doors, door frames, storage shelving and bins, and other fixtures?

Yes: Cleaning occurs monthly.

Yes: Disinfecting occurs monthly.

Yes: A sporicidal agent is applied monthly.

2.5.9.2) Cleaning, Disinfecting, and Sporicidal Agents

1) Cleaning, disinfecting and sporicidal information for the licensee.

Observation
USP 825 | Effective 12/01/2020
Cleaning and disinfecting agents must be selected and used with careful consideration of compatibilities, effectiveness, and user safety. Considerations when selecting and using disinfectants include their anti-microbial activity, inactivation by organic matter, residue, shelf life, preparation requirements of the agent, and suitability for surfaces being disinfected (see Disinfectants and Antiseptics □1072□). After the disinfectant is applied on the surface to be disinfected, the disinfectant must be allowed to dwell for the minimum contact time specified by the manufacturer, during which time the surface cannot be disturbed. Only the 70% IPA used in the ISO Class 5 PEC must be sterile. Sporicidal agents must be used at least monthly on all surfaces in classified areas and SRPAs. Some EPA-registered (or equivalent) one-step disinfectant cleaners may have sporicidal properties. See Table 6 for a summary of the purpose of the cleaning, disinfecting, and sporicidal agents.

2) Does the facility allow use an appropriate cleaning agents and allow it to dwell for the minimum contact time specified by the manufacturer?

Yes: The facility uses an appropriate cleaning agent.

Yes: The cleaning agent is allowed to dwell for the appropriate time.

Observation
Pharmacy uses sterile water

3) Does the facility use an appropriate disinfecting agent and allow it to dwell for the minimum contact time specified by the manufacturer?

Yes: The facility uses an appropriate disinfecting agent.

Yes: The disinfecting agent is allowed to dwell for the appropriate time.

Observation
Pharmacy uses 70% IPA

4) Does the facility use an appropriate sporicidal agent and allow it to dwell for the minimum contact time specified by the manufacturer?

Yes: The facility uses an appropriate sporicidal agent

Yes: The sporicidal agent is allowed to dwell for the appropriate time.

2.5.9.3) Cleaning Supplies

1) Are cleaning supplies disposable?

Yes: wipers and mop heads are low-lint and disposable

Yes: Disposable cleaning supplies are discarded after each cleaning activity.

2) Are reusable cleaning tools made of cleanable materials?

Yes: Reusable cleaning tools are made of cleanable materials.

Yes: Reusable cleaning tools are cleaned and disinfected before and after each use.

Yes: Reusable cleaning tools are dedicated for use in the classified areas or SRPAs and are not removed from these areas except for disposal.

Yes: Reusable cleaning tools are discarded after an appropriate amount of time based on their condition.

3) Are cleaning supplies and solutions used in the classified areas and SRPAs monitored for radioactive contamination after use and prior to disposal?

Yes:

4) Are cleaning supplies disposed of in a manner that minimizes the potential for dispersing particulates into the air?

Yes:

2.5.9.4) Cleaning and Disinfecting the PEC

1) Are PECs with removable work trays are cleaned and disinfected monthly?

Other:

Observation
N/A

2.5.9.5) Disinfecting Supplies for Classified Areas and SRPAs

1) Does the facility properly disinfect supplies prior to placing them in the classified area?

Yes: Shipping cartons or other corrugated or uncoated cardboard are allowed in classified areas (including the clean side of the anteroom and/or within the perimeter of the SRPA).

Yes: Items are wiped with an EPA registered sporicidal agent or equivalent one-step disinfectant cleaner, or sterile 70% IPA using low lint wipers.

Yes: Sporicidal/disinfecting agents are allowed to dwell on the surface for the minimum contact time specified by the manufacturer.

Yes: The agent used for disinfecting packaging are compatible with teh packaging and doe not render the product label unreadable.

2) Are all items transferred into the PEC from the classified area or SRPA disinfected with a sterile disinfectant?

Yes:

3) HOT CELL: If sterile packages are not able to be opened inside a ISO 5 hot cell, are they opened and appropriately labeled outside the ISO Class 5 environment and placed in disinfected shielding immediately prior to the dispensing cycle?

Yes: Sterile items opened prior to introduction in to the ISO 5 space are labeled.

Yes: Sterile items opened outside the ISO 5 space are immediately placed in disinfected shielding.

Yes: Sterile items opened outside the ISO 5 environment are done so immediately prior to the forthcoming dispensing cycle.

2.5.9.6) Disinfecting Critical Sites

1) Are critical sites wiped with sterile 70% IPA?

Yes: Sterile IPA is used for chemical disinfection.

Yes: Mechanical action (physically wiping) is used to remove contanimants.

Yes: Sterile 70% IPA is allowed to dry before piercing critical sites.

2.5.9.7) Cleaning and Disinfecting Items from Patient Care Area

1) Is radiation shielding equipment used in the classified area/SRPA or PEC that is exposed to patient care areas cleaned and disinfected before returning to any classified area?

Other:

Observation
N/A

2.5.10) Assigning BUDs

2) The facility assigns BUDs based on the preparation conditions of USP 825.

Yes: Dispensing, repackaging, preparation and preparation with minor deviations prepared in ISO 5 PEC or an SRPA are assigned a 12-hour BUD.

3) Does the facility extend BUDs longer than the manufacturer stated/suggested use-by time interval?

No: The facility does not extend BUDs beyond the manufacture stated/suggested time interval.

2.5.11) Documentation

2) Does the facility maintain records including policies and SOPs for personnel training involved in repackaging, preparing, preparing with minor deviations, compounding, and dispensing radiopharmaceuticals.

Yes: The facility has records of personnel training and testing including visual assessment of aseptic technique competency.
Yes: The facility has records of personnel training and testing for validation.
Yes: The facility has records of personnel training and testing for garbing and hand hygiene.
Yes: The facility has records of personnel training and testing for equipment and environment cleaning and disinfecting.
Yes: The facility has records of personnel training and testing for gloved fingertip and thumb sampling.
Yes: The facility has records of personnel training and testing for media fill evaluation.

3) Does the facility maintain records for testing and monitoring environmental controls?

Yes: The facility has records for monitoring environmental controls.
Yes: Testing/monitoring include ACPH and pressure differentials.
Yes: Testing/monitoring include viable air and surface sampling.
Yes: Testing/monitoring include total airborne particle test results.
Yes: Testing/monitoring include temperature and humidity.

4) Does the facility maintain records for equipment maintenance, and cleaning/disinfecting?

Yes:

5) Does the facility maintain records for end product radiochemical purity and other testing as applicable?

Yes: The facility maintains end product radiochemical purity tests.
Yes: The facility maintains other testing results.

6) Does the facility have master formula records for preparations with minor deviations to compounding?

Other:

Observation
N/A - pharmacy is not compounding with minor deviations.

7) Does the facility have records for stability testing which supports extended BUD dating?

Other:

Observation
N/A

8) Does the facility have records of investigations and corrective actions for preparation deviations?

Yes: Records of corrective actions are documented through the closure of the event.

9) Preparations with Minor Deviations: Do master formulas contain all the required information?

Other:

Observation
N/A

10) PREPARATIONS WITH MINOR DEVIATIONS: Do records of preparations with minor deviations contain all required information?

Other:

Observation
N/A

2.5.12.1) Preparation Following Manufacturer Instructions

1) Information for the licensee

Observation

USP 825| Effective 12/01/2020
The individual responsible for preparing the radiopharmaceutical(s) must ensure that the final preparation complies with quality and purity specifications throughout the assigned BUD. This includes, as appropriate for the preparation, radionuclidic purity, radiochemical purity, chemical purity, and physical and chemical properties.

2) NONSTERILE PREPARATIONS: Does the facility take into account appropriate radiation safety considerations and environmental controls when preparing radiopharmaceuticals according to manufacturer directions?

Other:

Observation
N/A

3) NONSTERILE PREPARATIONS: Is the area clean and uncluttered to ensure the overall integrity and quality of the radiopharmaceutical prepared according to the manufacturer directions?

Other:

Observation
N/A

4) STERILE PREPARATIONS: Does the facility have processes to maintain sterility of products compounded in accordance with manufacturer instructions?

Yes: Radiation safety considerations are in place.

Yes: Environmental controls are in place.

Yes: Aseptic handling practices are in place.

2.5.12.2) Preparation with Minor Deviations

1) Does the facility compound radiopharmaceuticals with minor deviations from the manufacturer instructions?

No:

2.5.12.3) Preparation of Radiolabeled Blood Components

2) Does the facility prepare radiolabeled blood components?

No:

2.5.12.4) Preparation of Radiolabeled Red Blood Cells for Immediate Use

1) Does the facility prepare radiolabeled red blood cells for immediate use?

No:

2.5.13.1) General Compounding

1) USP 825 FAQ Questions 72-79: Compounding

Observation

USP 825 | Effective 12/1/2023
USP FAQ for your information. Add as needed to individual inspections.

COMPOUNDING
72. Are radiopharmaceuticals compounded by 503B facilities or conventionally manufactured in FDA-registered drug establishments considered active pharmaceutical ingredients (APIs)?
No. The term "API" refers to a bulk drug substance (pure chemical substance), usually in powder or liquid form, which is intended to be used in compounding. API is distinguished from finished dosage forms.

73. Is kit-splitting (fractionation) allowed per ?
<825> defines standards that must be met if kit splitting is performed. In <825>, kit splitting is defined as the act of dividing the contents of kit vial and transferring aliquots into other containers for storage and subsequent radiolabeling. Section 11.2 states that kit-splitting may be used to meet the patient need. For example, the contents of a kit vial can be reconstituted with 0.9% sodium chloride injection and aliquoted into other containers for storage and subsequent radiolabeling. The individual must consider all possible interactions of kit components with these other containers (e.g., container walls, closures), as well as possible alterations in stability (e.g., physical and chemical stability) that may affect radiolabeling yields of performance parameters when determining an appropriate BUD. See Table 7. Preparation Conditions for Sterile Radiopharmaceuticals.

74. If a drug that has biological distribution in its USP monograph is fractionated under the 96-hour compounding standard

(Table 7) of what parameters need to be checked before using the fractionated product?
<825> does not specify what quality testing parameters are to be performed for compounded radiopharmaceuticals. As an example, if a user is fractionating a container of a conventionally manufactured, lyophilized drug product, Section 8. Assigning a BUD,states "the individual responsible for the manipulation assigns the BUD based on established testing data, either performed in-house or obtained from peer reviewed literature. Section 8 also states that the BUD is also dependent on maintenance of appropriate quality and purity, including radiochemical purity, radionuclidic purity, and other applicable parameters as specified in individual monographs or as clinically appropriate. In addition section 11.2 states "The individual responsible must consider all possible interactions of kit components with these other containers (e.g., container walls, closures), as well as possible alterations in stability (e.g., physical stability, chemical stability) that may affect radiolabeling yields or performance parameters, when determining an appropriate BUD. Systematic QC testing is required to validate the appropriateness of a particular BUD. If a drug product is compounded with non-sterile components, section 11.3 Sterile Compounding Using a Nonsterile Drug Substance or Components applies.

75. If an area in a hospital is designated as "Radiopharmacy", does it then require a Pharmacy Sterile compounding license and a qualified Pharmacist to be involved with compounding of these products?
Depending on the state, "radiopharmacy" may be used synonymously with "nuclear pharmacy" vis-à-vis licensing by the state board of pharmacy. In a nuclear medicine department or clinic, the common term "hot lab" is used to denote an area for radiopharmaceuticals but is not a pharmacy per se that would require separate licensure from the state board of pharmacy. In either situation, compounding is performed under the supervision of an Authorized User Physician or Authorized Nuclear Pharmacist.

76. Does compounding include radiolabeling of kits according to the package insert?
No, please refer to the Glossary in <825> for USP's definitions of radiopharmaceutical compounding, preparation, and preparation with minor deviations.

77. Is a master drug formulation record required to use an FDA-approved radiopharmaceutical for an unapproved use?
Section 9.1 states that an"MFR is required only for a preparation with minor deviations or compounding". Approved and unapproved indications of radiopharmaceuticals relates to the procedure and usage of the drug which is beyond the scope of the preparation or compounding of the drug. An MFR is required if the radiopharmaceutical is prepared with a minor deviation or compounded regardless of whether the indication is approved or not in the FDA prescribing information.

78. When is a CoA required for radiopharmaceutical sterile compounding?
When a sterile radiopharmaceutical compounding activity involves the use of a bulk drug substance (which includes a radionuclide, a ligand, or other substance such as a precursor that becomes an active ingredient in the final radiopharmaceutical), Section 11.3 states that it "must comply with standards of an applicable USP or NF monograph, if one exists, or be a component of an approved drug product. Each bulk drug substance should be manufactured by drug establishments registered with FDA and be accompanied by a valid CoA or equivalent testing procedures."

79. Does USP require a certificate of analysis for an FDA approved product if you are preparing with minor deviations or compounding?
Under 9.1 Master Formulation Record it states an MFR is required for a preparation with minor deviations or compounding; examples of data that must be included are name, identity, strength, purity, quality, and quantity of ingredients with validated documentation (e.g., CoA). While a CoA is an example of one type of validated documentation, the Prescribing Information of the FDA approved product is also a valid example

3) Does each compounding activity have a pre-established written procedure?

Observation

USP | Effective 12/01/2020
Each compounding activity must be based on a pre-established written procedure and must include maintenance of compounding records. The compounding record must provide traceability (see 9. Documentation - 19.5.11).

4) Is all sterile compounding performed using aseptic technique in an ISO 5 PEC?

Yes: Aseptic technique is used for sterile compounding.

Yes: Sterile compounding is performed in an ISO 5 PEC.

5) Does the facility compound radiopharmaceuticals that have been withdrawn from the market because of safety or lack of effectiveness?

No:

6) Does the facility compound radiopharmaceuticals that are an essential copy of a marketed FDA-approved radiopharmaceutical?

No:

2.5.13.2) Compounding Nonsterile Radiopharmaceuticals

2) Are areas for nonsterile compounding appropriate for radiopharmaceutical compounding?

Other:

Observation
N/A

2.5.13.3) Sterile Compounding

1) Does the facility sterile compound by adding conventionally manufactured products to the radiopharmaceutical?

No:

2.5.13.4) Sterile Compounding Using a Nonsterile Drug Substance or Components

1) Does the facility perform a sterilization procedure when compounding with one or more non-sterile ingredients to make a sterile product?

Other:

Observation
Pharmacy does not use non-sterile starting ingredients, so does not need to perform sterilization procedures.

2.5.14.1) Dispensing and Radioassay

2) Does the facility radioassay all final doses?

Yes: All final doses are radioassayed except for unopened manufacturer containers.
Yes: Measured activity is mathematically corrected for radioactive decay to the time of the scheduled administration.
Yes: The activity at calibration time is always within federal, state and local variance limits.

2.5.14.2) Labeling

2) Are inner containers labeled with the minimum information required by USP 825?

Yes: Inner containers contain the standard radiation symbol.
Yes: Inner containers contain the words "Caution - Radioactive Material"
Yes: Inner containers for therapeutic and blood products contain the patient name/identifier.
Yes: Inner containers contain the radionuclide and chemical form (generic name).
Yes: Inner containers contain the radioactivity and the date and time of calibration.

3) Is the outer shielding labeled with the minimum information required by USP 825?

Yes: Outer shielding is labeled with the standard radiation symbol.
Yes: Outer shielding is labeled with the words "Caution- Radioactive Material".
Yes: Outer shielding of all therapeutic and blood products is labeled with the patient name/identifier.
Yes: Outer shielding is labeled with the radionuclide and chemical form (generic name).
Yes: Outer shielding is labeled with the radioactivity and the date and time of calibration.
Yes: Outer shielding is labeled with the volume or number of units dispensed.
Yes: Outer shielding is labeled with the product expiration date or BUD.
Yes: Outer shielding is labeled with special storage and handling instructions for non-immediate use.
Yes: Outer shielding is labeled with the route of administration.

2.5.14.3) Direct Infusion Systems

1) Does the facility use a direct infusion system?

No:

2.5.14.4) Transporting Generators Between Facilities.

1) Does the facility transport generators between facilities?

Yes:

2) Does the facility follow the UPS 825 standards for transporting generators between facilities?

Yes: The generator needle and/or ports are capped in ISO Class 8 air or better with sterile protectors.
Yes: The generator is packaged and transported in a manner to maintain the integrity and sterility of the generator system.

2.5.15) Repackaging

1) Does the facility repackage radiopharmaceuticals?

Yes.

2) Are repackaged radiopharmaceuticals radioassayed?

Yes.

3) Are inner containers of repackaged radiopharmaceuticals labeled according to USP 825 recommendations?

Yes. Repackaged radiopharmaceuticals are labeled with the standard radiation symbol.

Yes: Repackaged radiopharmaceuticals are labeled with the words "Caution -Radioactive Material".

Yes: Repackaged radiopharmaceuticals are labeled with teh radionuclide and chemical form (generic name).

Yes: Repackaged radiopharmaceuticals are labeled with the radioactivity with units at time of calibration and calibration time.

4) Is the outer shielding of repackaged radiopharmaceuticals labeled according to USP 825 recommendations?

Yes. Outer shielding is labeled with the standard radiation symbol.

Yes. Outer shielding is labeled with the words "Caution- Radioactive Material."

Yes. Outer shielding is labeled with teh radionuclide and chemical form (generic form).

Yes. Outer shielding is labeled with the radioactivity with units at time of calibration and the calibration time.

Yes. Outer shielding is labeled with the volume or number of units.

Yes: Outer shielding is labeled with the product expiration or BUD.

Yes. Outer shielding is labeled with special storage and handling instructions.

2.5.16.1) Quality Assurance and Quality Control

2) Does the facility have a formally established and SOP documented Quality Assurance Program?

Yes: The SOPs ensure that all aspects of handling of radiopharmaceuticals are conducted in accordance with USP 825, and applicable state and federal laws.

Yes. The Quality Assurance program establishes a system of adherence to procedures.

Yes. The Quality Assurance program establishes a system for the prevention and detection of errors and other quality problems.

Yes: The Quality Assurance program evaluates complaints and adverse events.

Yes: The Quality Assurance program provides for appropriate investigations and corrective actions.

3) Does the facility have a formally established Quality Control program?

Yes: The SOPs ensure that all aspects of handling of radiopharmaceuticals are conducted in accordance with USP 825, and applicable state and federal laws.

Yes. The Quality Control program establishes a system of adherence to procedures.

Yes. The Quality Control program establishes a system for the prevention and detection of errors and other quality problems.

Yes: The Quality Control program evaluates complaints and adverse events.

Yes: The Quality Control program provides for appropriate investigations and corrective actions.

4) Do facility SOPs describe the roles, duties and training of personnel responsible for each aspect of the QA program?

Yes.

5) Are QA and QC programs reviewed at least once every 12-months by the designated person?

Yes. The designated person reviews the QA and QC programs annually.

Yes: Results of the review are documented.

Yes. Appropriate corrective actions are taken if needed.

2.5.16.2) Notification About and Recall of Out-of-Specification Dispensed Radiopharmaceuticals

1) Does the facility dispense or administer radiopharmaceuticals before the results of release testing are known?

Yes.

Observation
Conditional release is performed with documentation to accompany.

2) Does the facility have SOPs in place for the notification and recall of out-of-specification dispensed radiopharmaceuticals?

Yes: SOPs are in place to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm.

Yes. SOPs are in place to determine when a recall is necessary.

3) Do SOPs for the recall of out-of-specification dispensed radiopharmaceuticals contain contain procedures required by USP 825?

Yes: SOPs contain procedures to determine the severity of the problem and the urgency for implementation and completion of the recall.

Yes: SOPs contain procedures to determine the distribution of any affected radiopharmaceuticals including the date and quantity.

Yes: SOPs contain procedures outlining the disposition and reconciliation of the recalled radiopharmaceutical.

Observation
TSA locks are present on the container, so products aren't released until quality control testing has resulted.

4) Does the facility document recalls and report them to the appropriate regulating body?

Yes. The facility has a procedure to document recalls, however they have not had any recalls.

2.5.16.3) Complaint Handling

1) Does the facility have SOPs for handling complaints?

Yes.

2) Does the designated person review all complaints?

Yes, complaints are reviewed to determine if they indicate a potential quality problem.

3) Is the complaint investigation complete?

Yes: The investigation considers if the quality problem could extend to other radiopharmaceuticals.

Yes: The investigation includes corrective actions.

Yes: The investigation allows for corrective action to be implemented for all potentially affected radiopharmaceuticals.

Yes: The investigation considers whether to initiate a recall.

Yes: The investigation considers whether to cease sterile compounding until all underlying problems have been identified and corrected.

4) Does the facility have readily retrievable records of each complaint, regardless of the source?

Yes. A readily retrievable record of each complaint is kept by the facility.

Yes: The records contain the name of the complainant.

Yes. The records contain the date the complaint was received.

Yes: The records contain the nature of the complaint.

Yes: The records contain the response to the complaint.

Yes: The records contain the name and strength of the radiopharmaceutical and the assigned internal identification number (if known).

Yes: The records include the findings of any investigation and follow-up.

Yes: Records are readily retrievable for review and evaluation.

Yes. Records are used to evaluate possible trends.

Yes. Records are retained.

Observation
Has not received any complaint.

5) Are radiopharmaceuticals returned in connection with a complaint quarantined until destruction after the completion of the investigation.

Yes.

Observation
Discussed procedures, as pharmacy has not had any returned/complaint products.

2.5.16.4) Adverse Event Reporting

1) Are adverse events potentially associated with the quality of radiopharmaceuticals reported in accordance with the facilities SOPs and all applicable jurisdictional laws and regulations?

Yes: Adverse events are reported to the State of Ohio Board of Pharmacy.

Yes. Adverse events are reported to the Ohio Department of Health.

Yes: Adverse events are reported to the FDA MedWatch program.

Yes: Adverse events are reported according to SOPs.

5) Additional Information/Observations

1) Additional Information/Observations

Observation

Certification conducted 5/19/2025:

- Particle counts hot cell 1: 16, 15, 86, 3, 3
- Particle counts hot cell 2: 47, 6, 14, 11, 7
- Pass through particle counts: 6, 0, 0, 0, 0
- Particle counts BSC: 0, 5, 0, 2, 0
- Particle counts buffer room: 2, 44, 75, 323, 91, 253
- Particle counts ante room: 93, 59, 144, 217, 319
- Surface buffer room table - 1 bacterial and 1 fungal growth; both below action levels

9) Substance Abuse and Mental Health Resources for Healthcare Professionals

1) Substance Abuse and Mental Health Resources for Healthcare Professionals

Observation

The healthcare profession is not immune to substance use disorder and mental health conditions. Such medical conditions impair a healthcare professional's competency, ability, and judgment. Substance use disorder and/or mental health conditions that are left untreated may not only cause a healthcare professional to risk their career, but may also endanger the life of a patient. These medical conditions can be effectively treated, and it is possible for healthcare professionals that are in treatment or recovery to return to practice.

The State of Ohio Board of Pharmacy encourages all healthcare professionals who may be struggling with substance use disorder or mental health condition to seek help. The following are resources that can assist healthcare professionals in getting help: (The resources listed here are for informational purposes only and do not constitute an endorsement by the State of Ohio Board of Pharmacy. They do not represent a complete list of the resources available)

Ohio Careline 1-800-720-9616, emotional support, with referral to other resources if needed.
Crisis text line, text "4hope" to 741 741 to speak with a crisis counselor.
Treatment Bridge 1-877-275-6364, for addiction and mental health services.
National Suicide prevention dial 988, or call 1-800-273-8255.
Ohio Domestic Violence Network 1-800-934-9840
Pharmacist Rehabilitation Organization (www.ohiopro.org) for pharmacists and pharmacy interns.
Ohio Physicians Health Program (www.ophp.org)

10) Inspection Affirmation

1) Inspection Affirmation

Observation
*This document only addresses compliance with the rules or laws specifically identified above.

As the person in charge at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent/Inspector, and understand its content.

If this inspection report requires a written response, I understand, per OAC 4729:5-3-03, that either of the following must be submitted to the State of Ohio Board of Pharmacy within 30 days of this inspection:
(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or
(2) An explanation disputing the observed violations.

I understand that if I am not the responsible person documented on this site's Ohio terminal distributor of dangerous drugs license, I will ensure the responsible person is provided a complete copy of this inspection report in a timely manner.

I further acknowledge that a written response does not release the licensee listed in this inspection report from potential disciplinary action.

Responses must be either emailed (with a copy of the inspection report) to WRITTENRESPONSE@PHARMACY.OHIO.GOV or mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

No Issue Found

Reviewed by Cameron Grahl

(signature)

Board of Pharmacy

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until March 31, 2027.

PharmaLogic Cincinnati, LLC

200 Albert Sabin Way Rm G310

Cincinnati, OH 45267-2800

License Number: 0230000021

License Type: Terminal - Pharmacy - Category 2

Sub-Category: NU – Nuclear Pharmacy

Expiration Date: March 31, 2027

Responsible Person – Print, sign, and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request in eLicense Ohio - elicense.ohio.gov.

Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

eLicense Ohio
Professional Licensure

License Look Up

12/16/2025 8:58 AM

PharmaLogic Cincinnati, LLC

License Number	0230000021
Status	Active
Sub-Status	
Board	Board of Pharmacy
License Type	Terminal - Pharmacy - Category 2
License Issue Date	4/25/23
License Expiration Date	3/31/27
License Effective Date	4/1/25
Street Address	200 Albert Sabin Way Rm G310
City	Cincinnati
State	OH
Zipcode	45267-2800
Country	United States
Board Action	No

Supervised By:

Supervisor Name	Supervisor License	Status	Start Date	End Date
Cameron Grahl	03442783	Active	Fri Feb 10 00:00:00 GMT 2023	

Current date & time: **12/16/2025 8:58 AM**

Disclaimer: The Joint Commission and NCQA consider on-line status information as fulfilling the primary source verification requirement for verification of licensure in compliance with their respective credentialing standards.

DEA Explanation

PharmaLogic Cincinnati, LLC (OH license number 0230000021) is a closed-door nuclear pharmacy that does not order, store, compound, dispense, or otherwise handle controlled substances, therefore a DEA registration is not required for operation of this facility.

4NN

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: [redacted] ☒ Non-sterile Compounding ☒ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: The Pharmacy Place

Physical Address: 2035 Commerce Dr N

City: Peachtree City State: GA Zip: 30269

Mailing Address (if different from physical address): (same address)

City: _____ State: _____ Zip: _____

Telephone: 8335863111 Toll Free # (NAC 639.708, NRS 639.23286): 8335863111

Fax: 6782713971 Contact Email: thepharmacyplacellc@gmail.com

Website: www.thepharmacyplace.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Jolyn Bennett

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 25111

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Jolyn Bennett	NV Pharmacist Registration #: 25111
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: NA

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: GA

Parent Company (if any):

Corporation/Organization Name: The Pharmacy Place LLC

Mailing Address: 2035 Commerce Dr N

City: Peachtree City State: GA Zip: 30269

Telephone: 8335863111 Email: thepharmacyplacellc@gmail.com

Contact Person Name: Hiren Patel

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: NA

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: NA

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President and Owner (title) for The Pharmacy Place (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Hiren Patel

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

07/15/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hiren Patel

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

07/15/2026

Date

Board Use Only	Date Received: 7/23/26	Amount: $500.00

Control Number : 15082248

STATE OF GEORGIA

Secretary of State

Corporations Division
313 West Tower
2 Martin Luther King, Jr. Dr.
Atlanta, Georgia 30334-1530

CERTIFICATE OF EXISTENCE

I, **Brad Raffensperger**, the Secretary of State of the State of Georgia, do hereby certify under the seal of my office that

THE PHARMACY PLACE LLC
a Domestic Limited Liability Company

was formed in the jurisdiction stated below or was authorized to transact business in Georgia on the below date. Said entity is in compliance with the applicable filing and annual registration provisions of Title 14 of the Official Code of Georgia Annotated and has not filed articles of dissolution, certificate of cancellation or any other similar document with the office of the Secretary of State.

This certificate relates only to the legal existence of the above-named entity as of the date issued. It does not certify whether or not a notice of intent to dissolve, an application for withdrawal, a statement of commencement of winding up or any other similar document has been filed or is pending with the Secretary of State.

This certificate is issued pursuant to Title 14 of the Official Code of Georgia Annotated and is prima-facie evidence that said entity is in existence or is authorized to transact business in this state.

Docket Number	: 31822051
Date Inc/Auth/Filed	: 08/24/2015
Jurisdiction	: Georgia
Print Date	: 06/25/2026
Form Number	: 211

Brad Raffensperger

Brad Raffensperger
Secretary of State

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: The Pharmacy Place

Pharmacy/Wholesaler License # (if applicable): new app

Physical Address: 2035 Commerce Dr N

City: Peachtree City State: GA Zip: 30269

Mailing Address (if different from physical address): (same address)

City: State: Zip:

Telephone: 8335863111 Website: www.thepharmacyplace.com

Licensing Company Email: thepharmacyplacellc@gmail.com

Section 2: Personal Information

First: Hiren Middle: Last: Patel

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Peachtree City State: GA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
South University			08/05 - 05/08	
Address	City		State	Zip
709 Mall Blvd	Savannah		GA	31406
Diploma/Degree obtained, if any				
Doctor of Pharmacy				
School Name			From - To (MM/YY – MM/YY)	
GA State University			08/02 - 05/05	
Address	City		State	Zip
100 Auburn Ave	Atlanta		GA	30303
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Claxton High School			08/98 - 05/02	
Address	City		State	Zip
600 Herlrix Street	Claxton		GA	30417
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/18 - Current	[redacted]	Peachtree City	GA	[redacted]
04/09 - 11/18	[redacted]	Peachtree City	GA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
The Pharmacy Place			04/16 – Current	
Business Address	**City**		**State**	**Zip**
2035 Commerce Dr N	Peachtree City		GA	30269
Phone	**Title**		**Number of Employed Hours**	
678-271-5970	Pharmacist/Owner		20,000	
Description of Duties				
Pharmacy Manager				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7/4/2026
Date

I, Miten Patel, certify that as the designated representative for The Pharmacy Place,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. HP I am at least 21 years of age;
3. HP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. HP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. HP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. HP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. HP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Miten Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/4/2016

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hiren Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/15/2026

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Hiren Patel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/15/2026

Date

Subscribed and Sworn to before me this 15th day of July.

Mara Rachel Bogdanski

Notary Public Signature

MARA RACHEL BOGDANSKI NOTARY PUBLIC FAYETTE COUNTY, GA EXP. 11/3/2029 (Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: The Pharmacy Place

NV Pharmacy or Outsourcing facility license # (if applicable): new app

Physical Address: 2035 Commerce Dr N

City: Peachtree City State: GA Zip: 30269

Mailing Address (if different from physical address): (same address)

City: State: Zip:

Telephone: 8335863111 Toll Free # (NAC 639.708, NRS 639.23286): 8335863111

Fax: 6782713971 Contact Email: thepharmacyplacellc@gmail.com

Website: www.thepharmacyplace.com

Nevada Business License # (if applicable)

Supervising/Managing Pharmacist Name (NRS 639.220): Jolyn Bennett

Supervising/Managing Pharmacist NV Pharmacist Registration #: 25111

Name of Designated Person(s) as defined by revised USP-797 guidelines:

Email of Designated Person(s): thepharmacyplacellc@gmail.com

Telephone of Designated Person(s): 8335863111

5. What is the frequency for completing surface sampling? WEEKLY		
6. What is the frequency for using sporicidal agents? DAILY		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	(Yes)	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	(Yes)	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

HANNAH GRAY
Name of Person who Completed the Form

PHARMACIST / DESIGNATED PERSON
Title

Hannah Gray
Signature (copies or stamps not accepted)

6/24/26
Date

Board Use Only	Date Received: 7/25/26 Date Approved: _____ Approved By: _____

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

NEW 797 EMPLOYEES COMPLETE COMPETENCIES FOR THE FOLLOWING PRIOR TO COMPOUNDING IN 797: USE OF EQUIPMENT, ENVIRONMENTAL SAMPLING, ASEPTIC MANIPULATION, AUTOMATED COMPOUNDING DEVICES, CLEANING / DISINFECTION STERILE COMPOUNDING AREAS, CSP CALCULATIONS/MEASURING/MIXING, MATERIALS HANDLING IN STERILE COMPOUNDING ENVIRONMENTS, PEC LAMINAR AIRFLOW WORKBENCHES, RESPONSIBILITIES OF PERSONNEL IN STERILE COMPOUNDING, SECs, THESE COMPETENCIES ARE THEN SIGNED OFF FOR VISUAL COMPLETION OF APPROPRIATE TASKS BY THE DESIGNATED PERSONS. GARBING & MEDIA PERFORMED PRIOR TO COMPOUNDING.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

TIRZEPATIDE/NIACINAMIDE/CYANOCOBALAMIN

SEMAGLUTIDE/NIACINAMIDE/CYANOCOBALAMIN

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

EVERY 3 MONTHS

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? (Yes) No

4. What is the frequency for completing volumetric active air sampling?

ONCE MONTHLY

N/A

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)			
1. What type of primary engineering controls will you be using in your facility?			
2. Are you complying with all USP 800 guidelines?	N/A	Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	N/A	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	N/A	Yes	No
5. Do you have a negative pressure buffer room at your facility?	N/A	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?		Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?		Yes	No
8. Will you be utilizing a closed system transfer device?		Yes	No
9. If yes, list the name of the device:			

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

APPROPRIATE CAUTIONARY LABELS PROVIDED WITH MEDICATIONS.

13. What is your procedure for visual inspection of compounded sterile products?

THE VERIFYING PHARMACIST VISUALLY INSPECTS PRODUCTS FOR FINAL QUANTITY, COLOR, & PARTICULATES AGAINST A BLACK/WHITE BACKGROUND.

14. How often do you perform glove fingertip and medial fill testing?

EVERY 3 MONTHS

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

ALL STERILE COMPOUNDING PERSONNEL MUST PERFORM INITIAL GLOVEFINGERTIP TESTING x3, ~~THEN~~ AND MEDIA FILL. THIS ONGOING GLOVED FINGERTIP TESTING AFTER GARB & ONGOING MEDIA FILL IS THEN PERFORMED EVERY 3 MONTHS. INITIAL AND COMPETENCIES/TRAINING ARE COMPLETED THROUGH SIMPLIFI 797. QUARTERLY POTENCY CHECKS ON PERSONNEL ARE PERFORMED.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

- DAILY WHEN COMPOUNDING OCCURS - USING A STERILE LOW-LINT WIPER, ALL INSIDE SURFACES OF PEC/SEC AND EQUIPMENT WITHIN PEC/SEC CLEANED & DISINFECTED WITH STERILE PERIDOX RTU & ALLOWED TO DWELL FOR SPECIFIED CONTACT TIME. THEN STERILE IPA 70% APPLIED TO ALL EQUIPMENT & INTERIOR SURFACES OF PEC & ALLOWED TO DRY.
- STERILE 70% IPA APPLIED TO DIRECT COMPOUNDING AREA & HORIZONTAL WORK SURFACE OF PEC BEFORE INITIATING COMPOUNDING, PRIOR TO EACH BATCH, AT LEAST EVERY 30 MIN IF THE COMPOUNDING PROCESS TAKES 30MIN OR LESS, & TO REMOVE RESIDUE AFTER CLEANING/DISINFECTION.

17. Who performs the sterile compounding process at your facility?

JOLYN BENNETT, HANNAH CLAY, KYLE WILLIAMS, PRACHI PATEL, NILESH PATEL

18. Who is responsible and accountable for the sterile compounding process at your facility?

HANNAH CLAY

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy? REFRIGERATED PRODUCTS ARE PACKAGED IN A STYROFOAM COOLER WITH ICEPACKS TO REDUCE RISK OF TEMPERATURE EXCURSIONS. GLASS CONTAINERS ARE PROTECTED WITH BUBBLEWRAP. SHIPPING VALIDATION IS PERFORMED BIANNUALLY. STYROFOAM COOLER IS PLACED IN A CARDBOARD SHIPPING BOX.

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ☑ Category 2 ☑ Category 3

If you marked "**Category 3**", you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☑ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☑ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ☑ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? MARCH 2024

6. What is the frequency of the recertification for the ISO classified areas? EVERY 6 MONTHS

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ☑ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ☑ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? WEEKLY

10. Will you be performing sterile hazardous drug compounding? Yes ☑ No

If you marked "**Yes**", you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

TIRZEPATIDE/NIACINAMIDE/CYANOCOBALAMIN

SEMAGLUTIDE/NIACINAMIDE/CYANOCOBALAMIN

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL

Address: 840 RESEARCH PKWY STE. 546

City: OKLAHOMA CITY State: OK Zip: 73104

Telephone: 8003931595

Georgia Drugs and Narcotics Agency

Director
Michael E. Karnbach, Pharm.D.

Deputy Director
Alec T. Mathis, Jr. RPh.

254 Washington Street S.W. • Suite G2000 • Atlanta, Georgia 30334 • (404)656-5100 • GDNA.Office@GDNA.GA.GOV
www.GDNA.GA.GOV

STERILE COMPOUNDING

Pharmacy Permit Inspection

Purpose of Inspection: Routine
Inspection: INSP-25-579
Applicant:
Inspection Date: August 11, 2025

Agent: Nick Aderibigbe
Assisting Agent:

Facility Name: The Pharmacy Place
dba:
Facility License #: PHRE010257
License Exp Date: June 30, 2027
Address: 2035 Commerce Drive North , Peachtree City GA , 30269
County: Fayette
Phone #: 6782713970
Fax #: 6782713971
Facility Email: hiren@thepharmacyplace.com

Associated Licenses:
Cardinal Health - PHWH001232 - June 30, 2027 - Supplier
AmerisourceBergen Drug Corporation - PHWH004101 - June 30, 2027 - Supplier
PCCA - PHWH003471 - June 30, 2027 - Supplier
Medisca Inc - PHWH003095 - June 30, 2027 - Supplier
Inmar Rx Solutions Inc - PHRD000052 - June 30, 2027 - Reverse Distributor
Letco Medical LLC - PHWH003872 - June 30, 2027 - Supplier

Previous Inspection Number:
Inspection Date:

Exhibits:

Pharmacist in Charge License *RPH024644 - Hiren Patel*
PIC License Number *RPH024644*
PIC License Expiration Date *2026-12-31*
USP 797 Designated Person 1 *Hannah Gray*
USP 797 Designated Person 2

USP 797 Designated Person 3

A. Compounding Overview
1. Does this facility compound with nonhazardous drugs? *Yes*
Comments:

2. Does the facility compound with hazardous drugs (HDs)? *No*
Comments:

2.1 Was a USP 800 inspection conducted?
Comments:

NOTE: Handling of nonsterile hazardous drugs (HDs) must additionally comply with USP 800. [1]
3. What types of sterile preparations are compounded?
Comments:

B. Personnel Training and Evaluation

1. Before beginning to compound CSPs independently or have direct oversight of compounding personnel, have all personnel completed the following training initially and at least every 12 months in at least the following?
1.1 Is there documentation to show compounding personnel (and those with oversight of compounding personnel) have completed training and demonstrated knowledge of principles of hand hygiene before beginning to compound CSPs? This must be done initially and at least every 12 months. *Yes*

USP 797 Section 2.1
Comments:

1.2 Is there documentation to show compounding personnel (and those with oversight of compounding personnel) have completed training and demonstrated knowledge of principles of garbing before beginning to compound CSPs? This must be done initially and at least every 12 months. *Yes*

USP 797 Section 2.1
Comments:

1.3 Is there documentation to show compounding personnel (and those with oversight of compounding personnel) have completed training and demonstrated knowledge of principles of cleaning and disinfection before beginning to compound CSPs? This must be done initially and at least every 12 months. *Yes*

USP 797 Section 2.1
Comments:

1.4 Is there documentation to show compounding personnel (and those with oversight of compounding personnel) have completed training and demonstrated knowledge of principles of calculations, measuring, and mixing before beginning to compound CSPs? This must be done initially and at least every 12 months. *Yes*

USP 797 Section 2.1
Comments:

1.5 Is there documentation to show compounding personnel (and those with oversight of compounding personnel) have completed training and demonstrated knowledge of principles of aseptic technique before beginning to compound CSPs? This must be done initially and at least every 12 months. *Yes*

USP 797 Section 2.1
Comments:

1.6 Is there documentation to show compounding personnel (and those with oversight of compounding personnel) have completed training and demonstrated knowledge of principles of achieving and/or maintaining sterility (and apyrogenicity if compounding with nonsterile components) before beginning to compound CSPs? This must be done initially and at least every 12 months. *Reviewed*

USP 797 Section 2.1
Comments: *Training did not specifically document principles of achieving/maintaining sterility.*

1.7 Is there documentation to show compounding personnel (and those with oversight of compounding personnel) have completed training and demonstrated knowledge of principles of use of equipment before beginning to compound CSPs? This must be done initially and at least every 12 months. *Reviewed*

USP 797 Section 2.1
Comments: *Training did not specifically document use of equipment*

1.8 Is there documentation to show compounding personnel (and those with oversight of compounding personnel) have completed training and demonstrated knowledge of principles of documentation of the compounding process (e.g., master formulation and compounding records) before beginning to compound CSPs? This must be done initially and at least every 12 months. *Yes*

USP 797 Section 2.1
Comments:

1.9 Is there documentation to show compounding personnel (and those with oversight of compounding personnel) have completed training and demonstrated knowledge of principles of principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area before beginning to compound CSPs? This must be done initially and at least every 12 months. *Reviewed*

USP 797 Section 2.1
Comments: *Training did not specifically document principles of principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 ar*

1.10 Is there documentation to show compounding personnel (and those with oversight of compounding personnel) have completed training and demonstrated knowledge of principles of proper use of PECs before beginning to compound CSPs? This must be done initially and at least every 12 months. *Yes*

USP 797 Section 2.1
Comments:

1.11 Is there documentation to show compounding personnel (and those with oversight of compounding personnel) have completed training and demonstrated knowledge of principles of

movement of materials and personnel within the compounding area before beginning to compound CSPs? This must be done initially and at least every 12 months. *Yes*

USP 797 Section 2.1
Comments:

2. Have personnel who compound or have direct oversight of compounding personnel completed ongoing training? This training shall include:
2.1 Annual training and competency in sterile compounding principles and practices. *Yes*

USP 797 Section 2
Comments:

2.2 Garbing competency (including GFT) training shall be every 6 months for Category 1 and 2, every 3 months for Category 3, or every 12 months for the DP and personnel with direct oversight. *Yes*

USP 797 Section 2
Comments:

2.3 Media fill with post-GFT and surface sampling shall be every 6 months for Category 1 and 2, every 3 months for Category 3, or every 12 months for the DP and personnel with direct oversight. *Yes*

USP 797 Section 2
Comments:

3. Have personnel who restock or clean and disinfect the sterile compounding area completed training as defined by the facility's SOP's? *Yes*

USP 797 - Table 2. Initial Training and Competency
Comments:

4. Have personnel who perform in-process checks or final verification of CSPs completed training as defined by the facility's SOP's? *Yes*

USP 797 - Table 2. Initial Training and Competency
Comments:

5. Have personnel who only compound immediate-use CSPs completed training as defined by the facility's SOP's? *Not Inspected*

USP 797 - Table 2. Initial Training and Competency
Comments: *No immediate use CSP at this facility*

C. Personal Hygiene and Garbing
1. Does the facility use brushes or hand dryers for hand hygiene? *No*

USP 797 Section 3.2 Paragraph 1
Comments:

2. Was hand washing and/or garbing observed during this visit in compliance with USP 797 and the facility's SOPs? *No*

USP 797 Section 3.2 Paragraph 2
Comments: *No sterile compounding was conducted during inspection*

3. Were donning/doffing of sterile gloves observed during this visit in compliance with USP 797 and the facility's SOPs? *No*

USP 797 Section 3.3 Paragraph 5
Comments: *No sterile compounding was conducted during inspection*

4. Do personnel utilize sterile and powder free gloves? *Yes*

USP 797 Section 3.3 Paragraph 5
Comments:

5. Do personnel utilize sterile 70% IPA? *Yes*

USP 797 Section 3.3 Paragraph 5
Comments:

D. Facilities and Engineering Controls
1. Are the anteroom, buffer room, and SCA separated from areas not directly related to compounding? *Yes*

USP 797 Section 4 Paragraph 1
Comments:

2. Are temperature and humidity being monitored and recorded in each room of the cleanroom suite each day that compounding is performed? *Yes*

USP 797 Section 4.2 Paragraph 1
Comments:

3. Are the classified spaces or the SCA void of free-standing air conditioners, humidifiers, and dehumidifiers? *Yes*

USP 797 Section 4.2 Paragraph 1
Comments:

4. Is the ISO-classified anteroom and buffer room separated from the surrounding unclassified areas by fixed walls and doors? *Yes*

USP 797 Section 4.2.1 Paragraph 2
Comments:

5. Are the classified rooms equipped with a pressure-differential monitoring system? *Yes*

USP 797 Section 4.2.1 Paragraph 2
Comments:

6. Is air supplied to the cleanroom suite introduced through HEPA filters that are located in the ceiling of the buffer room and anteroom? *Yes*

USP 797 Section 4.2.1 Paragraph 2

Comments:

7. Are air returns in the cleanroom suite low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow? *Yes*

USP 797 Section 4.2.1 Paragraph 3
Comments:

8. Does the anteroom have a line of demarcation to separate the clean side from the dirty side, or it is designed with two separate anterooms-a dirty anteroom and a clean anteroom? *Yes*

USP 797 Section 4.2.1 Paragraph 4
Comments:

9. Does placement of the PECs allow for cleaning around the PEC? *Yes*

USP 797 Section 4.2.3 Paragraph 1
Comments:

10. Is the RABS located in the SCA only utilized to prepare Category 1 CSPs? Are RABS utilized to compound Category 2 or Category 3 CSPs located within a cleanroom suite with an ISO Class 7 or better buffer room with an ISO Class 8 or better anteroom? *Not Inspected*

USP 797 Section 4.2.3 Paragraph 6
Comments: *No RABS used at the facility*

11. Is the positive pressure differential between the buffer room and anteroom not less than of 0.020-inch water column? *Yes*

USP 797 Section 4.2.5 Paragraph 1
Comments:

12. Is the positive pressure differential between the anteroom and the unclassified area not less than 0.020-inch water column? *Yes*

USP 797 Section 4.2.5 Paragraph 1
Comments:

13. Is the negative pressure differential between the C-SEC and the adjacent area between 0.01 and 0.03-inch water column? *Not Inspected*

USP 800 Section 5.3 Paragraph 1
Comments: *No hazardous sterile compounding conducted at the facility*

14. Where pressure differentials are required, is a pressure differential monitoring device used to continuously monitor the pressure differentials? Are the quantitative results from the pressure monitoring device reviewed and documented at least daily on the days when compounding is occurring? *Yes*

USP 797 Section 4.2.5 Paragraph 2
Comments:

15. Are presterilization procedures using non-sterile components performed in single-use containment glove bags, containment ventilated enclosures (CVEs), BSCs, or CACIs in an ISO Class 8 or better environment? *Yes*

USP 797 Section 4.2.6 Paragraph 1
Comments:

16. In the cleanroom suite: Are the surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area smooth, impervious, free from cracks and crevices, and nonshedding? *Yes*

USP 797 Section 4.3.1 Paragraph 1
Comments:

17. In the cleanroom suite: Are junctures between the ceiling and the walls and between the walls and the floor sealed? *Yes*

USP 797 Section 4.3.1 Paragraph 1
Comments:

18. In the cleanroom suite: For ceilings that consist of inlaid panels, are the panels caulked around each panel to seal them to the support frame? *Yes*

USP 797 Section 4.3.1 Paragraph 1
Comments:

19. In the cleanroom suite: Are walls constructed of, or covered with, durable material (e.g., epoxy painted walls or heavy-gauge polymer) and the integrity of the surface maintained? Are panels joined together and sealed to each other and the support structure? *Yes*

USP 797 Section 4.3.1 Paragraph 2
Comments:

20. In the cleanroom suite: Do floors include coving to the sidewall, or are the juncture between the floor and the wall caulked? *Yes*

USP 797 Section 4.3.1 Paragraph 2
Comments:

21. In the cleanroom suite: Are the exterior lens surfaces of ceiling light fixtures smooth, mounted flush, and sealed? *Yes*

USP 797 Section 4.3.1 Paragraph 2
Comments:

22. In the segregated compounding area (SCA): Are all surfaces (e.g., walls, floors, counters, and equipment) clean, uncluttered, and dedicated to compounding? *Not Inspected*

USP 797 Section 4.3.2
Comments: *NO SCA*

23. Does the buffer room contain plumbed water sources [e.g., sink(s), eyewash(es), shower(s), or floor drain(s)]? *No*

USP 797 Section 4.4 Paragraph 2
Comments:

24. Is the anteroom free of floor drain(s)? *Yes*

USP 797 Section 4.4 Paragraph 2
Comments:

25. Is only furniture, equipment, and other materials necessary for performing compounding activities in the classified area or SCA? *Yes*

USP 797 Section 4.5 Paragraph 1
Comments:

26. Are the classified areas or SCA free of shipping carton(s) or other corrugated or uncoated cardboard? *Yes*

USP 797 Section 4.5 Paragraph 1
Comments:

27. Are carts used to transport components or equipment into classified areas constructed from nonporous materials with cleanable casters and wheels? *Yes*

USP 797 Section 4.5 Paragraph 2
Comments:

E. Certification and Recertification

1. Has the compounding area been independently certified initially and every 6 months thereafter as stated in USP Chapter 797 Section 5 to include the following?

USP 797 Section 5 Paragraph 1
Comments:

1.1 Is a dynamic airflow smoke pattern test performed in the PEC under dynamic operating conditions? *Yes*

USP 797 Section 5 Paragraph 2
Comments:

1.2 Were HEPA filter integrity tests conducted? *Yes*

USP 797 Section 5 Paragraph 2
Comments:

1.3 Was total particle count testing conducted in all classified areas (e.g., in the ISO Class 5 PEC and ISO Class 7 and 8 rooms) durmg dynamic operating conditions? *Yes*

USP 797 Section 5 Paragraph 2
Comments:

1.4 Was the number of personnel present in each PEC and SEC during total particle-count tests and dynamic airflow smoke-pattern tests documented? *Yes*

USP 797 Section 5 Paragraph 4
Comments:

2. Has the compounding area been independently certified initially and every 6 months thereafter as stated in USP Chapter 797 Section 4 include the following?
2.1 Is a minimum of 30 total HEPA-filtered ACPH supplied to ISO Class 7 rooms? *Yes*

USP 797 Section 4.2.4 Paragraph 3
Comments:

2.2 Is a minimum of 20 total HEPA-filtered ACPH supplied to ISO Class 8 rooms? *Yes*

USP 797 Section 4.2.4 Paragraph 4
Comments:

2.3 Was the positive pressure differential between the buffer room and anteroom is not less than 0.020-inch water column? *Yes*

USP 797 Section 4.2.5 Paragraph 1
Comments:

2.4 Was the positive pressure differential between the anteroom and the unclassified area is not less than 0.020-inch water column? *Yes*

USP 797 Section 4.2.5 Paragraph 1
Comments:

3. If levels measured during the total air sampling program exceed the criteria established in USP 797 for the ISO classification of the area sampled, was the cause investigated and corrective action taken and documented? Was data collected in response to corrective actions reviewed to confirm that the actions taken were effective? *Yes*

USP 797 Section 5.1 Paragraph 3
Comments:

4. Are the CVEs, BSCs, or CACIs used for presterilization procedures of non-sterile components certified at least every 6 months? *Yes*

USP 797 Section 4.2.6 Paragraph 1
Comments:

F. Microbiological Air and Surface Monitoring
1. Are microbiological air and surface monitoring performed initially for sterile compounding facilities? *Yes*

USP 797 Section 6.1 Paragraph 4
Comments:

2. Are regular review of the microbiological airborne and surface sampling data performed to detect trends and are the results of the review documented? *Yes*

USP 797 Section 6.1 Paragraph 2
Comments:

3. Does the facility have a monitoring program for viable airborne particles developed and implemented to include the following?:

USP 797 Section 6
3.1 Is volumetric active air sampling taken of all classified areas using an impaction air sampler in each classified area [e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)] during dynamic operating conditions every 6 months for entities compounding Category 1 and Category 2 CSPs? *Yes*
Comments:

3.2 For entities compounding any Category 3 CSPs, is volumetric active air sampling completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs? *Not Inspected*
Comments: *No Category 3 compounding*

3.3 Is the incubation of microbiological growth media used for air sampling documented and conducted in compliance with USP 797? *Yes*
Comments:

3.4 If levels measured during the viable air monitoring program exceed the levels established in USP 797 for the ISO classification levels of the area sampled, is the cause investigated and corrective action taken? *Yes*
Comments:

4. Were surface samples taken from each classified area, including each room and the interior of each ISO Class 5 PEC and pass-through chambers connecting to classified spaces? *Yes*

USP 797 Section 6.3.1 Paragraph 1
Comments:

5. For entities compounding Category 1 and Category 2 CSPs, were surface sampling of all classified areas, and pass-through chambers connecting to classified areas, conducted at least monthly? *Yes*

USP 797 Section 6.3.1 Paragraph 4
Comments:

6. For entities compounding any Category 3 CSPs, were surface sampling of all classified areas, and pass-through chambers connecting to classified areas, completed prior to assigning a BUD longer than the limits established in USP 797 Table 13, and at least weekly on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs *Not Inspected*

USP 797 Section 6.3.1 Paragraph 5
Comments: *No Category 3 compounding*

7. Is surface sampling conducted within the PEC used to prepare Category 3 CSPs, at the end of each batch before cleaning and disinfection occurs, unless a self-enclosed robotic device is used? When a self-enclosed robotic device is used as the PEC to prepare Category 3 CSPs, is surface sampling conducted at least once daily at the end of compounding operations, before cleaning and disinfection occurs? *Not Inspected*

USP 797 Section 6.3.1 Paragraph 5
Comments: *No Category 3 compounding*

8. Is incubation of microbiological growth media used for surface sampling documented and conducted in compliance with USP 797. *Yes*

USP 797 Section 6.3.2 Paragraph 1
Comments:

9. If levels measured during surface sampling exceed the levels established in USP 797 for the ISO classification levels of the area sampled, is the cause investigated and corrective action taken? *Yes*

USP 797 Section 6.3.3 Paragraph 1
Comments:

G. Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA
1. Are surfaces of the sink(s) cleaned and disinfected each day of use, and is a sporicidal disinfectant applied at least monthly? *Yes*

USP 797 Section 4.4 Paragraph 1
Comments:

2. If compounding was observed during this visit, was sterile 70% IPA applied to the horizontal work surface, including any removable work trays, of the PEC at least every 30 min if the compounding process takes 30 min or less? If the compounding process took more than 30 min was the work surface of the PEC disinfected immediately after compounding? *Yes*

USP 797 Section 7 Paragraph 2
Comments:

3. Did documentation show the following were cleaned and disinfected daily on days when compounding occurred?:

USP 797 - Table 10. Minimum Frequency for Cleaning and Disinfecting Surfaces and Applying Sporicidal Disinfectants in Classified Areas and in the SCA
3.1 PEC(s) and equipment inside the PEC(s) *Yes*
Comments:

3.2 Pass-through chambers *Yes*
Comments:

3.3 Work surface(s) outside the PEC *Yes*
Comments:

3.4 Floor(s) *Yes*
Comments:

4. Did documentation show the following areas were cleaned, disinfected, and a sporicidal disinfectant was applied monthly?:

USP 797 - Table 10. Minimum Frequency for Cleaning and Disinfecting Surfaces and Applying Sporicidal Disinfectants in Classified Areas and in the SCA
4.1 Wall(s), door(s), and door frame(s) *Yes*
Comments:

4.2 Ceiling(s) *Yes*
Comments:

4.3 Storage shelving and bin(s) *Yes*
Comments:

4.4 Equipment outside the PEC(s) *Yes*
Comments:

5. Did documentation show a sporicidal disinfectant was applied monthly for entities compounding Category 1 and/or Category 2 CSPs or weekly for entities compounding Category 3 CSPs for the following areas?

USP 797 - Table 10. Minimum Frequency for Cleaning and Disinfecting Surfaces and Applying Sporicidal Disinfectants in Classified Areas and in the SCA
5.1 PEC(s) and equipment inside the PEC(s) *Yes*
Comments:

5.2 Pass-through chambers *Yes*
Comments:

5.3 Work surface(s) outside the PEC *Yes*
Comments:

5.4 Floor(s) *Yes*
Comments:

6. If items were observed being introduced into the PEC, were they wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use as outlined in USP 797? *Reviewed*

USP 797 Section 8.2
Comments:

Notes

H. Equipment, Supplies and Components
1. Do personnel maintain records from equipment calibration, verification, and maintenance? *Yes*

USP 797 Section 9.1 Paragraph 2
Comments:

2. Do compounding personnel maintain a daily record of the accuracy measurements on the days the equipment is used? *Yes*

USP 797 Section 9.1 Paragraph 4
Comments:

3. Are corrective actions implemented if accuracy measurements are outside the manufacturer's specification? *Yes*

USP 797 Section 9.1 Paragraph 4
Comments:

4. Is the date of receipt by the compounding facility clearly marked on each API or added substance package that lacked a vendor expiration date? *Yes*

USP 797 Section 9.3.2 Paragraph 3

Comments:

5. Were packages of components (i.e., API and added substances) that lacked a vendor's expiration date assigned a conservative expiration date, not to exceed 1 year after receipt by the compounding facility? *Yes*

USP 797 Section 9.3.2 Paragraph 3
Comments:

6. Do personnel monitor temperature in the area(s) where components are stored either manually at least once daily on days that the facility is open or by a continuous temperature recording device to determine whether the temperature remains within the appropriate range? *Yes*

USP 797 Section 9.3.4 Paragraph 2
Comments:

I. Sterilization and Depyrogenation
1. Does the pharmacy perform dry heat depyrogenation to render glassware, metal, and other thermostable containers and components pyrogen free? *Yes*
Comments:

1.1 Was there documentation to show the effectiveness of the dry heat depyrogenation cycle established initially and verified annually using ECVs to demonstrate that the cycle is capable of achieving a >=3-log reduction in endotoxins? *Yes*

USP 797 Section 10.1 Paragraph 2
Comments:

2. Does the pharmacy have items that are not thermostable? *No*
Comments:

2.1 Were these depyrogenated by multiple rinses with sterile, nonpyrogenic water (e.g., Sterile Water for Injection or Sterile Water for Irrigation) and then thoroughly drained or dried immediately before use in compounding?

USP 797 Section 10.1 Paragraph 3
Comments:

3. Does the pharmacy use filtration as a method sterilization? *Yes*
Comments:

3.1 Were filter units used to sterilize CSPs subjected to the manufacturers' recommended integrity testing, such as a post-use bubble point test? *Yes*

USP 797 Section 10.2 Paragraph 2
Comments:

3.2 Were multiple filters required for the compounding process? *No*

USP 797 Section 10.2 Paragraph 2
Comments:

3.3 Did each of the filters pass a filter-integrity test? *Yes*

USP 797 Section 10.2 Paragraph 2
Comments:

4. Does the pharmacy use steam heat as a method of sterilization? *No*
Comments:

4.1 Were the date, run, and load numbers of the steam sterilizer used to sterilize the CSP documented in the compounding record?

USP 797 Section 10.3 Paragraph 6
Comments:

4.2 Was the effectiveness of steam sterilization verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus?

USP 797 Section 10.3 Paragraph 5
Comments:

5. Does the pharmacy use dry heat as a method of sterilization? *No*
Comments:

5.1 If sterilization by dry heat was used, were the date, run, and load numbers of the steam sterilizer used to sterilize the CSP documented in the compounding record?

USP 797 Section 10.4 Paragraph 4
Comments:

5.2 Was the effectiveness of dry heat sterilization verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Bacillus atrophaeus?

USP 797 Section 10.4 Paragraph 4
Comments:

J. Master Formulation and Compounding Records
1. Is a master formulation record created for all CSPs prepared from nonsterile ingredient(s) or CSPs prepared for more than one patient? *Yes*

USP 797 Section 11.1
Comments:

1.1 Do the master formulation records include at least the following information?:
1.1.1 Name, strength or activity, and dosage form of the CSP *Yes*

USP 797 - Box 9. Master Formulation Records
Comments:

1.1.2 Identities and amounts of all ingredients; if applicable, relevant characteristics of components (e.g., particle size, salt form, purity grade, solubility) *Yes*

USP 797 - Box 9. Master Formulation Records
Comments:

1.1.3 Type and size of container closure system(s) *Yes*

USP 797 - Box 9. Master Formulation Records
Comments:

1.1.4 Complete instructions for preparing the CSP, including equipment, supplies, a description of the compounding steps, and any special precautions *Yes*

USP 797 - Box 9. Master Formulation Records
Comments:

1.1.5 Physical description of the final CSP *Yes*

USP 797 - Box 9. Master Formulation Records
Comments:

1.1.6 BUD and storage requirements *No*

USP 797 - Box 9. Master Formulation Records
Comments: *MFR did not document storage requirements (refrigeration). Was corrected prior to conclusion of inspection*

1.1.7 Reference source to support the stability of the CSP *Yes*

USP 797 - Box 9. Master Formulation Records
Comments:

1.1.8 Quality control (QC) procedures (e.g., pH testing, filter integrity testing) *Yes*

USP 797 - Box 9. Master Formulation Records
Comments:

1.1.9 Other information as needed to describe the compounding process and ensure repeatability (e.g., adjusting pH and tonicity; sterilization method, such as steam, dry heat, irradiation, or filter) *Yes*

USP 797 - Box 9. Master Formulation Records
Comments:

2. Are compounding records (CR) created for all Category 1, Category 2, and Category 3 CSPs? NOTE: A CR must also be created for immediate-use CSPs prepared for more than one patient. When all of the conditions listed in USP 797 1.3 are met, compounding of CSPs for direct and immediate administration (to begin within 4 hours following the start of preparation) is not subject to the requirements for Category 1, Category 2, or Category 3 CSPs. The CR must be created to document the compounding process. A prescription or medication order or label may serve as the CR. *Yes*

USP 797 Section 11.2
Comments:

2.1 Do the compounding records include at least the following information?:
2.1.1 Name, strength or activity, and dosage form of the CSP *Yes*

USP 797 - Box 10. Compounding Records

Comments:

2.1.2 Date and time of preparation of the CSP *Yes*

USP 797 - Box 10. Compounding Records
Comments:

2.1.3 Assigned internal identification number (e.g., prescription, order, or lot number) *Yes*

USP 797 - Box 10. Compounding Records
Comments:

2.1.4 A method to identify the individuals involved in the compounding process and individuals verifying the final CSP *Yes*

USP 797 - Box 10. Compounding Records
Comments:

2.1.5 Name of each component *Yes*

USP 797 - Box 10. Compounding Records
Comments:

2.1.6 Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s) *Yes*

USP 797 - Box 10. Compounding Records
Comments:

2.1.7 Weight or volume of each component *Yes*

USP 797 - Box 10. Compounding Records
Comments:

2.1.8 Strength or activity of each component *Yes*

USP 797 - Box 10. Compounding Records
Comments:

2.1.9 Total quantity compounded *Yes*

USP 797 - Box 10. Compounding Records
Comments:

2.1.10 Final yield (e.g., quantity, containers, number of units) *Yes*

USP 797 - Box 10. Compounding Records
Comments:

2.1.11 Assigned BUD and storage requirements *No*

USP 797 - Box 10. Compounding Records
Comments: *Compounding record did not document storage requirements (refrigeration). Was corrected prior to conclusion of inspection*

2.1.12 Results of QC procedures (e.g., visual inspection, filter integrity testing, pH testing) *Yes*

USP 797 - Box 10. Compounding Records
Comments:

2.1.13 MFR reference for the CSP (if applicable) *Yes*

USP 797 - Box 10. Compounding Records
Comments:

2.1.14 Calculations made to determine and verify quantities and/or concentrations of components (if applicable) *Yes*

USP 797 - Box 10. Compounding Records
Comments:

K. Release Inspections and Testing
1. Is sterility testing conducted for Category 2 CSPs assigned a BUD that requires sterility testing according to USP 71 or a validated alternative method that is noninferior to USP 71 testing? *Yes*

USP 797 Section 12.2 Paragraph 1
Comments:

2. Is sterility testing conducted for all Category 3 CSPs according to USP 71 or a validated alternative method that is noninferior to USP 71 testing? *Not Inspected*

USP 797 Section 12.2 Paragraph 1
Comments: *No category 3 CSP's*

3. Is testing for bacterial endotoxins conducted for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing according to USP 85? *Yes*

USP 797 Section 12.3
Comments:

4. Is testing for bacterial endotoxins conducted for Category 3 injectable CSPs compounded from one or more nonsterile component(s) according to USP 85? *Not Inspected*

USP 797 Section 12.3
Comments: *No category 3 CSP's*

L. Labeling

1. In addition to other items required on a prescription label, are CSPs labeled with the following?:
1.1 Assigned internal identification number (e.g., prescription, order, or lot number) *Yes*

USP 797 Section 13 Paragraph 2
Comments:

1.2 Active ingredient(s) and their amount(s), activity(ies), or concentration(s) *Yes*

USP 797 Section 13 Paragraph 2
Comments:

1.3 Storage conditions if other than controlled room temperature *Yes*

USP 797 Section 13 Paragraph 2
Comments:

1.4 BUD *Yes*

USP 797 Section 13 Paragraph 2
Comments:

1.5 Dosage form *Yes*

USP 797 Section 13 Paragraph 2
Comments:

1.6 Total amount or volume if it is not obvious from the container *Yes*

USP 797 Section 13 Paragraph 2
Comments:

1.7 If it is in a single-dose container, a statement stating such when space permits *Yes*

USP 797 Section 13 Paragraph 2
Comments:

1.8 If it is in a multiple-dose container, a statement stating such *Yes*

USP 797 Section 13 Paragraph 2
Comments:

1.9 Route(s) of administration (if applicable) *Yes*

USP 797 Section 13 Paragraph 2
Comments:

1.10 Special handling instructions (if applicable) *Yes*

USP 797 Section 13 Paragraph 2
Comments:

1.11 Warning statements (if applicable) *Yes*

USP 797 Section 13 Paragraph 2
Comments:

M. Establishing Beyond-Use Dates
1. Did the immediate-use compounding records reviewed during the inspection show BUDs consistent with USP 797? *Not Inspected*

USP 797 Section 1.3 Paragraph 1 #6
Comments: *No immediate use compounding*

2. Did the category 1 compounding records reviewed during the inspection show BUDs consistent with USP 797? *Not Inspected*

USP 797 - Table 12. BUD Limits for Category 1 CSPs
Comments: *No category 1 compounding*

3. Did the category 2 compounding records reviewed during the inspection show BUDs consistent with USP 797? *Yes*

USP 797 - Table 13. BUD Limits for Category 2 CSPs
Comments:

4. Did the category 3 compounding records reviewed during the inspection show BUDs consistent with USP 797? *Not Inspected*

USP 797 - Table 14. BUD Limits for Category 3 CSPs
Comments: *No category 3 compounding*

N. SOPs
1. Were SOPs reviewed initially and at least every 12 months by the designated person(s) to ensure that they reflect current practices, and was the review documented? *Yes*

USP 797 Section 17

Does the pharmacy have standard operating procedures (SOPs) for the following (if applicable):Blood-derived and other biological materialsTraining and competency in aseptic processesTraining for compounding only immediate-use CSPsTraining for restocking or cleaning and disinfecting dutiesTraining and evaluating individuals who compound or have direct oversight of compounding personnelIncubation temperaturesRequired garb, manner of storage, and order of garbingDisinfection procedures for reusable equipmentChanging RABS sleeves and glovesTemperature and humidity readingsSampling sites and proceduresMicrobiological air and surface monitoringIncubator temperature monitoring and reviewFrequency, method(s), and location(s) of cleaning, disinfecting, and applying sporicidal disinfectantsCalibration, maintenance, cleaning, and use of the equipmentManipulating components that could generate airborne chemical particlesSelection, receipt, evaluation, handling, storage, and documentation of all CSP componentsTerminal sterilization and depyrogenation processInvestigations of defects that indicate sterility or stability problems to determine the causeLabeling proceduresTypes of CSPs that are prepared (i.e., Category 1, Category 2, Category 3)QA and QC programsRoles, duties, and training of the personnel responsible for each aspect of the QA programComplaint handlingAdverse event reportingHandling, storing, packaging, and transporting CSPsTraining and evaluating individuals who perform in-process checks, final verification, and dispensing of CSPsReuse of sterile 70% IPAChanges to MFR
Comments:

O. 480-11
1. Are compounded drug preparations based on the existence of a pharmacist/patient/prescriber relationship or anticipation of a prescription? *Yes*

Board of Pharmacy Rule [480-11-.02 (1)(a)]
Comments:

2. Are bulk drugs, chemicals, or materials used in compounding properly stored? *Yes*

Board of Pharmacy Rule [480-11-.04 (1)(b)]
Comments:

3. Is sewage, trash and other refuse disposed of in a safe and sanitary manner? *Yes*

Board of Pharmacy Rule [480-11-.04 (1)(d)]
Comments:

4. Do physical requirements stated in Board of Pharmacy Rule 480-11-.04 for compounding sterile products include the following?

Board of Pharmacy Rule 480-11-.04
4.1 Designated sterile compounding area *Yes*
Comments:

4.2 Adequate ventilation and lighting *Yes*
Comments:

4.3 Washing areas easily accessible to the compounding area *Yes*
Comments:

4.4 Sink with hot and cold running water *Yes*
Comments:

4.5 Soap or detergent; hand washing soap with bactericidal action *Yes*
Comments:

4.6 Laminar airflow hood (ISO 5) located within a clean room, or barrier isolator, etc. *Yes*
Comments:

4.7 Facility for light and dark field examination *No*
Comments: *Did not observe light and dark field examination facility*

4.8 Appropriate disposal containers for syringes and cytotoxic waste (if applicable) *Yes*
Comments:

4.9 A properly vented Class II, vertical flow BSC or appropriate barrier isolator if required *Yes*
Comments:

4.10 Refrigerator/freezer in working condition (with temperature monitored) *Yes*
Comments:

4.11 If compounding using components which must be weighed, Class A Balance with an assortment of metric weights or a Class I or II Electronic Balance *Yes*
Comments:

4.12 Disposable syringes and other supplies needed for compounding *Yes*
Comments:

4.13 Appropriate filters and filtration equipment *Yes*
Comments:

4.14 Oncology drug spill kit (if applicable) *Yes*
Comments:

5. Do additional requirements stated in USP Chapter 797 for compounding sterile products include the following?

USP 797 Section 3
5.1 Low-lint disposable towels or wipers *Yes*
Comments:

5.2 Alcohol-based hand rub *Yes*
Comments:

6. Do physical requirements stated in USP Chapter 797 Section 7 for compounding sterile products include cleaning and disinfecting agents? *Yes*

USP 797 Section 7.1.1
Comments:

7. Does the facility have appropriate references for sterile compounding? *Yes*

Board of Pharmacy Rule [480-11-.04 (5)]
Comments:

8. Are approved variances from the Board of Pharmacy posted (if applicable)? *Not Inspected*

Board of Pharmacy Rule [480-11-.04 (6)(b)]
Comments: *No variance/ exemptions*

9. Are procedures and records required by 480-11 retained for a minimum of two years? Note: These records may be kept as originals, photocopies, electronic files or other means of accurate reproduction. *Yes*

Board of Pharmacy Rule 480-11-.08 (1) and (2)
Comments:

10. Can all records and reports be produced immediately to the Georgia State Board of Pharmacy or GDNA if stored on site or within 48 hours if maintained in a central database? *Yes*

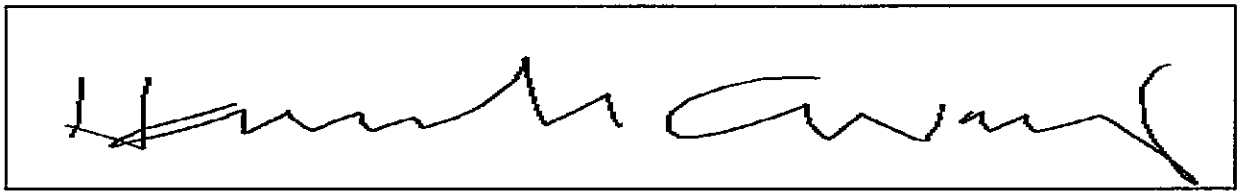
Board of Pharmacy Rule 480-11-.08 (3)
Comments:

Notes *The facility has a cleanroom suite. An ISO-8 classified anteroom (dry) with a certified containment hood, which leads to an ISO-8 anteroom (wet), and then to an ISO-7 buffer room.The facility was last certified by Equitech on 3/13/25 with all viable air/surface samples within acceptable ranges. Facility compounds GLP-1s (Tirzepitaide & Semaglutide) and states that they differ from readily available products based on the strength and their formulations contain B Vitamins.*

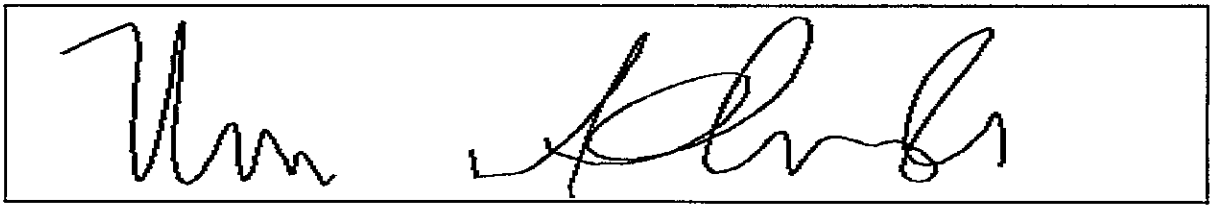
This inspection report has been read and explained to the pharmacist whose name appears below. Explanations include any observed violations, deficiencies, or comments, and such are based on state/federal laws and rules pertaining to the practice of pharmacy in the State of Georgia. I do

affirm the information I have given pursuant to this inspection is true and correct to the best of my knowledge. This inspection report is not intended to be all inclusive, and there may be deficiencies, non-compliance, or violations of the laws and rules not detected and noted in this report.

Facility Email: hiren@thepharmacyplace.com



Printed Name: Hannah Gray
Inspection Date: August 11, 2025



Printed Name: Nick Aderibigbe, Special Agent, Georgia Drugs & Narcotics Agency
Inspection Date: August 11, 2025

Georgia Drugs and Narcotics Agency

Director
Michael E. Kambach, Pharm.D.

Deputy Director
Alec T. Mathis, Jr. RPh.

254 Washington Street S.W. • Suite G2000 • Atlanta, Georgia 30334 • (404)656-5100 • GDNA.Office@GDNA.GA.GOV
www.GDNA.GA.GOV

RETAIL

Pharmacy Permit Inspection

Purpose of Inspection: Routine
Inspection: INSP-25-578
Applicant:
Inspection Date: August 11, 2025

Agent: Nick Aderibigbe
Assisting Agent:

Facility Name: The Pharmacy Place
dba:
Facility License #: PHRE010257
License Exp Date: June 30, 2027
Address: 2035 Commerce Drive North , Peachtree City GA , 30269
County: Fayette
Phone #: 6782713970
Fax #: 6782713971
Facility Email: hiren@thepharmacyplace.com

Associated Licenses:
Cardinal Health - PHWH001232- June 30, 2027 - Supplier
Inmar Rx Solutions Inc - PHRD000052- June 30, 2027 - Reverse Distributor
West End Pharmacy - PHRE009636- June 30, 2027 - Central Fill Facility
Fairmount Drugs Inc - PHRE011032- June 30, 2027 - Central Fill Facility
ADP Holdings LLC - PHRE010401- June 30, 2027 - Central Fill Facility
J&R 96 Holdings, LLC - PHRE011095- June 30, 2027 - Central Fill Facility
AmerisourceBergen Drug Corporation - PHWH004101- June 30, 2027 - Supplier

Previous Inspection Number:
Inspection Date:

Exhibits:
- Exhibit - Pharmacy Roster

Pharmacist in Charge *RPH024644 - Hiren Patel*
PIC License Number *RPH024644*

PIC License Expiration Date *2026-12-31*

A. Personnel
1. Do the above listed pharmacists have an active license/registration with the Board? *Yes*

Georgia Pharmacy Practice Act 26-4-40
Comments:

2. Is the above facility located at the address listed on the permit? *Yes*

Pharmacy Practice Act OCGA 26-4-110 (a)
Comments:

3. Is a pharmacist on duty and providing direct supervision of pharmacy personnel? *Yes*

Board of Pharmacy Rule 480-10-.02(1)(a)
Comments:

4. Does the pharmacy have a designated pharmacist-in-charge and is this the person on file with the Board of Pharmacy? *Yes*

Board of Pharmacy Rule 480-10-.01 (3)
Comments:

5. Were pharmacy personnel identifiable in a manner that displays name and job function? *Yes*

Board of Pharmacy Rule 480-15-.03 (c)
Comments:

6. Were any unlicensed or unregistered personnel found to be performing a function that requires a license or registration from the Board? *No*

Georgia Pharmacy Practice Act 26-4-80
Comments:

7. Were any technicians found to be performing functions that require the professional judgment of a pharmacist? *No*

Pharmacy Practice Act 26-4-82(a)
Comments:

8. Was the pharmacist to technician/intern/extern ratio compliant during this inspection? *Yes*

Pharmacy Practice Act 26-4-82(d) and (e)
Comments:

B. Facility
1. Is the pharmacy a minimum of 150 square feet? *Yes*

Board of Pharmacy Rule 480-10-.04
Comments:

2. Is the pharmacy clean and sanitary? *Yes*

Pharmacy Practice Act 26-4-110 (h)
Comments:

3. Is the pharmacy equipment clean and sanitary? *Yes*

Board of Pharmacy Rule 480-10-.08
Comments:

4. Does the pharmacy have the following equipment and supplies: *Yes*

Board of Pharmacy Rule 480-10-.12 (1)
Comments:

5. Is the pharmacy capable of being closed and locked to prevent unauthorized entry? *Yes*

Board of Pharmacy Rule 480-10-.02 (4) (a) (2)
Comments:

6. Is the prescription department permanently enclosed with a partition from floor to ceiling? *Yes*

Board of Pharmacy Rule 480-10-.16 (1) (a)
Comments:

C. General Questions
1. Does the pharmacy maintain all prescriptions (in their original format) for a minimum of two years? *Yes*

Board of Pharmacy Rule 480-27-.05
Comments:

2. Are prescription drugs stored in the prescription department in a secure manner? *Yes*

Board of Pharmacy Rule 480-10-.03
Comments:

3. Have outdated and deteriorated drugs been removed from stock? *Yes*

Board of Pharmacy Rule 480-10-.11
Comments:

4. Are syringes kept in the prescription department and only distributed by a pharmacist or intern/extern? *Yes*

Board of Pharmacy Rule 480-10-.13
Comments:

5. Does the pharmacy maintain printed dispensing records that are signed by a pharmacist or does the pharmacy maintain dispensing records electronically and the pharmacist signs a bound logbook attesting to their accuracy? *Yes*

Board of Pharmacy Rule 480-27-.05 (b)
Comments:

6. Does the pharmacy have a process to offer patient counseling as required? *Yes*

Pharmacy Practice Act 26-4-85(b)
Comments:

7. Does the pharmacy accept previously dispensed prescription drugs? *No*
7.1. Is the acceptance of previously dispensed prescription drugs in compliance with state and/or federal law or regulation?

Board of Pharmacy Rule 480-5-.03 (l)
Comments:

8. Does the pharmacy submit information regarding each controlled substance prescription dispensed to the prescription drug monitoring program (PDMP) at least every 24 hours? *Yes*

Controlled Substances Act OCGA 16-13-59 (b)
Comments:

9. Do dangerous drug (noncontrolled substance) prescriptions meet the requirements of a prescription drug order? *Yes*

Controlled Substances Act OCGA 16-13-74
Comments:

10. Does the pharmacy send dispensed prescriptions to a licensed medical practitioner to hold, administer, or deliver to the patient? *No*
10.1 Does the pharmacy obtain written authority from the patient to allow the pharmacy to send the prescriptions to the licensed medical practitioner?

Board of Pharmacy Rule 480-16-.02 (3)
Comments:

D. Controlled Substances
1. Does the pharmacy have a DEA registration? *Yes*
Comments:

1.1 Do schedule II controlled substance prescriptions meet the requirements of a prescription drug order? *Yes*

Controlled Substances Act OCGA 16-13-41 (b)
Comments:

1.2 Are schedule II controlled substance prescriptions filed and stored correctly? *Yes*

Board of Pharmacy Rule 480-22-.04 (7)
Comments:

1.3 Are schedule II controlled substance prescriptions signed by a pharmacist upon dispensing? *Yes*

Board of Pharmacy Rule 480-22-.04 (2)
Comments:

1.4 Do schedule III-V controlled substance prescriptions meet the requirements of a prescription drug order? *Yes*

Controlled Substances Act OCGA 16-13-41(d)(2)
Comments:

1.5 Has the pharmacy conducted a DEA Biennial Inventory? *Yes*

Controlled Substances Act OCGA 16-13-39
1.5.1 What is the date of the last DEA Biennial Inventory? *2025-03-06*
Comments:

1.6 Does the pharmacy sell exempt narcotics? *No*
Comments:

1.6.1 Does the pharmacy maintain records of all exempt narcotic sales that include the signature, date of birth, address, city, state, zip code of the purchaser as well as the date of such transaction, the name, kind, quantity and intended use of each product?

Board of Pharmacy Rule 480-19-.01 (b)
Comments:

1.7 Does the pharmacy sell over-the-counter medications that contain pseudoephedrine? *Yes*
Comments:

1.7.1 Does the pharmacy have a current DEA Combat Methamphetamine Self-Certification? *Yes*

Board of Pharmacy Rule 480-19-.03 (a)(2)
Comments:

1.7.2 Does the pharmacy electronically track all such sales and submit the required information to a real-time electronic logging system? *Yes*

Controlled Substances Act OCGA 16-13-30.3 (c)(4)
Comments:

E. Suppliers/Reverse Distributors

List all suppliers of compounded preparations and manufactured products under "Associated Licenses."
1. Are the suppliers licensed by the Georgia Board of Pharmacy? *Yes*

Board of Pharmacy Rule 480-10-.21
Comments:

2. Does a pharmacist on duty sign the invoice(s), including signature, legible Georgia pharmacist license number, and date, for all controlled substances upon receipt and verification? *Yes*

Board of Pharmacy Rule 480-10-.01 (1) (b)
Comments:

List all reverse distributors under "Associated Licenses."
3. Are the reverse distributors licensed by the Georgia Board of Pharmacy? *Yes*

Board of Pharmacy Rule 480-10-.14

Comments:

4. Does the pharmacy sell or otherwise transfer non-patient specific, manufactured prescription medication to other licensed entities (i.e., pharmacies, practitioners, etc)? *No*
4.1 Are these other entities licensed properly?

Board of Pharmacy Rule 480-7-.02 (g)
Comments:

4.2 Does the pharmacy maintain accurate records for transactions of controlled substances received and distributed in a manner that is readily retrievable for two years?

Georgia Controlled Substances Act OCGA 16-13-39
Comments:

4.3 Does the pharmacy maintain accurate records for transactions of dangerous drugs (noncontrolled substances) that are received and distributed in a manner that is readily retrievable for two years?

Georgia Dangerous Drug Act OCGA 16-13-72
Comments:

F. Vaccinations
1. Does the pharmacy administer vaccinations through a protocol agreement? *Yes*
Comments:

1.1 Does each administering pharmacist have a signed vaccine protocol agreement with a physician that is renewed biennially? *Yes*

Medical Practice Act OCGA 43-34-26.1 (b)
Comments:

1.2 Does each administering pharmacist have a signed and notarized affidavit that confirms the locations where vaccinations will be administered, they have completed the required training, and they maintain the appropriate liability insurance? *Yes*

Medical Practice Act OCGA 43-34-26.1 (d)
Comments:

1.3 Does the pharmacy provide the vaccine recipient with a Vaccine Information Statement from the Centers for Disease Control and Prevention? *Yes*

Medical Practice Act OCGA 43-34-26.1 (d)
Comments:

1.4 Does each patient sign and date a consent form that acknowledges receipt of the Vaccine Information Statement, consents to the administration of the vaccine, and authorizes the pharmacy to notify the patient's primary care provider? *Yes*

Medical Practice Act OCGA 43-34-26.1 (d)
Comments

1.5 Does the pharmacy report administered vaccinations to Georgia Registry of Immunization Transactions and Services (GRITS)? *Yes*

Medical Practice Act OCGA 43-34-26.1 (d) (9)
Comments:

1.6 Do vaccination administration records contain: the administering pharmacist; the name, dose, manufacturer, and lot number of the vaccine; the vaccine recipient's name, address, date of birth, and telephone number; the date of administration and injection site? *Yes*

Medical Practice Act OCGA 43-34-26.1 (d)
Comments:

1.7 Are vaccinations administered in a manner that maintains patient privacy? *Yes*

Medical Practice Act OCGA 43-34-26.1 (d)
Comments:

1.8 Do technicians administer vaccinations on behalf of the pharmacist? *No*
Comments:

1.8.1 Has each administering technician completed the required training?

Pharmacy Practice Act 26-4-52(c)
Comments:

Notes

G. Compounding
1. Does the pharmacy compound prescription medications? *Yes*
Comments:

1.1 Does the pharmacy compound nonsterile products? *Yes*
Comments:

1.1.1 Was a nonsterile compounding inspection conducted during this visit? *No*
Comments:

1.2 Does the pharmacy compound sterile products? *Yes*
Comments:

1.2.1 Was a sterile compounding inspection conducted during this visit? *Yes*
Comments:

1.3 Does the pharmacy compound hazardous drugs? *Yes*
1.3.1 Was a hazardous compounding inspection conducted during this visit? *No*
Comments:

H. Delivery
1. Does the pharmacy deliver prescriptions to patients by a contract carrier or by an employee of the pharmacy? *No*
Comments:

1.1 Does the pharmacy deliver controlled substances to patients by a contract carrier or by an employee of the pharmacy?
Comment

1.2 Does the pharmacy require a signature from the patient/caregiver for controlled substance prescriptions delivered by a contract carrier or an employee of the pharmacy?

Board of Pharmacy Rule 480-48-.03
Comments:

2. Does the pharmacy deliver prescriptions to patients by mail (via USPS or a commercial common carrier)? *Yes*
Comments:

2.1 Does the pharmacy deliver any drug requiring temperature control other than 'room temperature storage' prescriptions to patients by mail (via USPS or a commercial common carrier)? *Yes*
Comments

2.1.1 Does the pharmacy ensure the integrity of any drug requiring temperature control other than 'room temperature storage' that is delivered by mail? *Yes*

Board of Pharmacy Rule 480-48-.02 (3)
Comments:

2.2 Does the pharmacy deliver controlled substance prescriptions to patients by mail (via USPS or a commercial common carrier)? *No*
Comments

2.2.1 Does the pharmacy require a signature upon delivery for controlled substance prescriptions mailed to the patient?

Board of Pharmacy Rule 480-48-.02 (4)
Comments:

2.3 Does the pharmacy replace compromised prescription medication by next-day delivery or arrange for a minimum of a 7-day supply to be dispensed by a pharmacy of the patient's choice? *Yes*

Board of Pharmacy Rule 480-48-.02 (4)
Comments:

2.4 Does the pharmacy provide written information for patient counseling and a method for the patient to communicate with a pharmacist/intern? *Yes*

Board of Pharmacy Rule 480-48-.02 (4)
Comments:

2.5 Does the pharmacy document when the prescription was mailed to the patient? *Yes*

Board of Pharmacy Rule 480-48-.02 (4)
Comments:

2.6 Does the pharmacy make contact information for the Georgia Board of Pharmacy available to the patient for prescriptions mailed to the patient? *Yes*

Board of Pharmacy Rule 480-48-.02 (4)
Comments:

I. Central Fill
1. Does this pharmacy receive prescription medications from a central fill facility? *No*
Comments:

List facilities from which the pharmacy received central fill prescriptions under "Associated Licenses."
1.1 Are the central fill pharmacies licensed by the Georgia Board of Pharmacy?

Board of Pharmacy Rule 480-10A-.02 (1)
Comments:

1.2 Does a pharmacist/intern/technician sign for the receipt of all central fill prescriptions?

Board of Pharmacy Rule 480-10A-.05 (4)
Comments

1.3 Does a pharmacist verify the receipt of controlled substance prescriptions from the central fill pharmacy?

Board of Pharmacy Rule 480-10A-.06 (4)
Comments:

1.4 Are central fill prescriptions that are received by this pharmacy properly labeled to include: date of fill or refill; originating pharmacy name, address, and telephone number; central fill pharmacy's unique identifier; serial number of the prescription; name of the patient; name of the prescribing practitioner; expiration date of the dispensed drug; and directions for use and cautionary statements, if any, contained in such prescription or required by law.

Board of Pharmacy Rule 480-10A-.05 (6)
Comments:

1.5 Does this pharmacy and the central fill pharmacy have either a contract/agreement or are they under common ownership?

Board of Pharmacy Rule 480-10A-.02 (2)
Comments:

2. Does this pharmacy perform central fill services for another pharmacy? *Yes*
Comments:

List facilities from which the pharmacy sends central fill prescriptions under "Associated Licenses."
2.1 Are central fill prescriptions that are distributed by this pharmacy properly labeled to include: date of fill or refill; originating pharmacy name, address, and telephone number; central fill pharmacy's unique identifier; serial number of the prescription; name of the patient; name of the prescribing practitioner; expiration date of the dispensed drug; and directions for use and cautionary statements, if any, contained in such prescription or required by law. *Yes*

Board of Pharmacy Rule 480-10A-.05 (6)
Comments:

2.2 Does this pharmacy and the originating pharmacy have either a contract/agreement or are they under common ownership? *Yes*

Board of Pharmacy Rule 480-10A-.02 (2)
Comments:

J. Drive-Through
1. Does the pharmacy have a drive-through? *No*
Comments:

1.1 Is the drive-through window located in the wall of the pharmacy and can the pharmacist view the patient through this window?

Board of Pharmacy Rule 480-10-.16 (8)(a)
Comments:

1.2 Does the drive-through have no more than two (2) drive-through lanes?

Board of Pharmacy Rule 480-10-.16 (8)(a)
Comments:

1.3 Does the drive-through utilize a pneumatic tube system?
Comments:

1.3.1 Does the drive-through's pneumatic tube system originate in the prescription drug area of the pharmacy and does it terminate in a secure terminal in the drive-through?

Board of Pharmacy Rule 480-10-.16 8(b)(3)
Comments:

K. Emergency Service Providers
1. Does the pharmacy provide prescription medications to the emergency service provider? *No*
Comments:

1.1 Does the pharmacy have a signed contract/agreement with the medical director of the emergency service provider?

Pharmacy Practice Act OCGA 26-4-116(b)
Comments:

1.2 Does the pharmacy maintain a record of all the drugs issued to and used by the emergency service provider?

Pharmacy Practice Act OCGA 26-4-116
Comments:

1.3 Does the pharmacy physically inspect the drugs of the emergency service provider at least annually?

Pharmacy Practice Act OCGA 26-4-116(f)
Comments:

L. Informational Questions

1. Does the pharmacy use an Automated Pharmacy System (APS) or a Robotic Pharmacy System (RPS)? *Yes*
Comments:

2. Is the pharmacy registered as an authorized collector with the Board of Pharmacy? *No*
Comments:

3. Does the pharmacy provide emergency kits to other entities? *No*
Comments:

4. Does the pharmacy provide prescription medications to long-term care facilities? *No*
Comments:

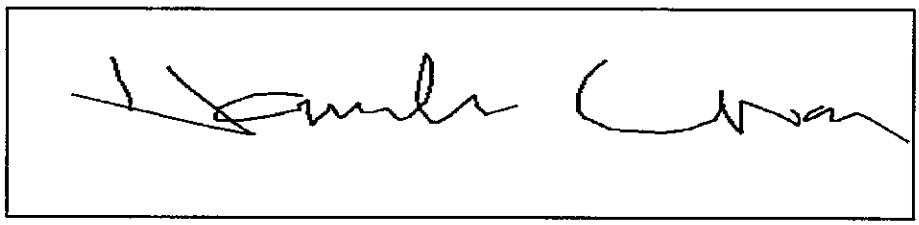
5. Does the pharmacy conduct remote prescription drug order processing for any other pharmacy? *No*
Comments:

6. Do any other pharmacies conduct remote prescription order processing for this pharmacy? *No*
Comments:

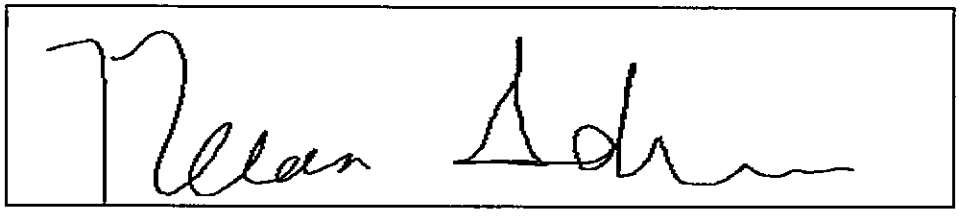
Notes

This inspection report has been read and explained to the pharmacist whose name appears below. Explanations include any observed violations, deficiencies, or comments, and such are based on state/federal laws and rules pertaining to the practice of pharmacy in the State of Georgia. I do affirm the information I have given pursuant to this inspection is true and correct to the best of my knowledge. This inspection report is not intended to be all inclusive, and there may be deficiencies, non-compliance, or violations of the laws and rules not detected and noted in this report.

Facility Email: hiren@thepharmacyplace.com



Printed Name: Hannah Gray
Inspection Date: August 11, 2025



Printed Name: Nick Aderibigbe, Special Agent, Georgia Drugs & Narcotics Agency
Inspection Date: August 11, 2025

Georgia Drugs and Narcotics Agency

Director
Michael E. Kambach, Pharm.D.

Deputy Director
Alec T. Mathis, Jr., RPh.

254 Washington Street S.W. • Suite G2000 • Atlanta, Georgia 30334 • (404)656-5100 • GDNA.Office@GDNA.GA.GOV
www.GDNA.GA.GOV

HAZARDOUS DRUGS COMPOUNDING

Pharmacy Permit Inspection

Purpose of Inspection: Routine
Inspection: INSP-25-589
Applicant:
Inspection Date: August 11, 2025
Agent: Nick Aderibigbe
Assisting Agent:

Facility Name: The Pharmacy Place
dba:
Facility License #: PHRE010257
License Exp Date: June 30, 2027
Address: 2035 Commerce Drive North , Peachtree City GA 30269
County:
Phone #: 6782713970
Fax #: 6782713971
Facility Email: hiren@thepharmacyplace.com

Associated Licenses:

Previous Inspection:
Inspection Date:

Exhibits:

Pharmacist In Charge *RPH024644 - Hiren Patel*
PIC License Number *RPH024644*
PIC License Expiration Date *2026-12-31*
USP 800 Designated Person 1 *Nilesh Patel*
USP 800 Designated Person 2
USP 800 Designated Person 3

A. Type of Hazardous Drug Compounding
1. Does this facility prepare compounded nonsterile preparations (CNSPs) with hazardous drugs (HDs)? *Yes*
Comments

1.1 Does the facility handle HD active pharmaceutical ingredient (API) for nonsterile preparations? *Yes*
Comments

1.2 Does the facility handle antineoplastic requiring HD manipulation for nonsterile preparations? *No*
Comments

2. Does this facility prepare compounded sterile preparations (CSPs) with hazardous drugs? *No*
Comments

2.1 Does the facility handle HD active pharmaceutical ingredient (API) for sterile preparations?
Comments

2.2 Does the facility handle antineoplastic requiring HD manipulation for sterile preparations?
Comments

3. Does this facility receive compounded preparations from outside sources? *No*
Comments

B. List of Hazardous Drugs - Assessment of Risk
1. Does the facility have a list of hazardous drugs (HDs)? *Yes*

USP 800 Section 2 Paragraph 1
2. When was the last documented review date? *2025-08-08*
3. Does documentation demonstrate the list is reviewed at least every 12 months? *Yes*

USP 800 Section 2 Paragraph 1
Comments

4. Does the facility have an assessment of risk for all hazardous drugs where required by USP 800? *No*

USP 800 Box 1: Containment Requirements
Comments *Unable to produce assessment of risk*

5. When was the last documented review date?
6. Does documentation demonstrate that the assessment of risk is reviewed at least every 12 months? *No*

USP 800 Section 2 Paragraph 4
Comments *Unable to produce assessment of risk*

C. Personnel Training and Evaluation

1. Are all personnel handling HDs trained based on their job functions before the employee independently handles HDs and reassessed at least every 12 months in the following?:

USP 800 Section 9
1.1 Overview of the entity's list of HDs and their risks *No*
Comments

1.2 Review of the entity's SOPs related to handling of HDs *Reviewed*
Comments *Training documentation did specify a review of the facilities SOP's*

1.3 Proper use of PPE *No*
Comments

1.4 Proper use of equipment and devices (e.g., engineering controls *No*
Comments

1.5 Response to known or suspected HD exposure *Yes*
Comments

1.6 Spill management *Yes*
Comments

1.7 Proper disposal of HDs and trace-contaminated materials *Yes*
Comments

Notes

D. Personal Hygiene and Garbing
1. Is PPE, including chemotherapy gloves, worn when unpacking HDs? *Yes*

USP 800 Section 10 Paragraph 2
Comments

2. Do personnel use the following when compounding sterile and nonsterile HDs?
2.1 HD gowns which resist permeability, close in the back, are long sleeved, and have closed cuffs that are elastic or knit. *Yes*

USP 800 Section 7.2 Paragraph 1
Comments

2.2 Head/hair covers *Yes*

USP 800 Section 7 Paragraph 2
Comments

2.3 Two pairs of shoe covers donned and doffed appropriately *Yes*

USP 800 Section 7.3 Paragraph 1
Comments

2.4 Two pairs of chemotherapy gloves (ASTM standard D6978) *Yes*

USP 800 Section 7 Paragraph 2
Comments

3. Is reusable PPE decontaminated and cleaned after use, and/or is disposable PPE not re-used? *Yes*

USP 800 Section 7 Paragraph 1
Comments

4. Is PPE placed in an appropriate waste container and further disposed of per local, state, and federal regulations? *Yes*

USP 800 Section 7.6
Comments

E. Facilities and Engineering Controls
1. Are there signs designating the entrance to HD handling areas? *Yes*

USP 800 Section 5 Paragraph 1
Comments

2. Are antineoplastic HDs and all HD APIs unpacked in an area that is neutral/normal or negative pressure? *Yes*

USP 800 Section 5.1
Comments

3. Are antineoplastic HDs requiring manipulation and any HD API stored separately from non-HDs in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH)? *Yes*

USP 800 Section 5.2 Paragraph 2
Comments

4. Are refrigerated antineoplastic HDs stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH? *Not Inspected*

USP 800 Section 5.2 Paragraph 4
Comments

5. Are sterile and nonsterile HDs compounded within a C-PEC located in a C-SEC? *Yes*

USP 800 Section 5.3.2 Paragraph 4
Comments

6. Does the C-SEC used for sterile and nonsterile compounding meet the following?:

USP 800 Section 5.3 Paragraph 2
Comments

6.1 Externally vented *Yes*
Comments

6.2 Physically separated (i.e., a different room from other preparation areas) *Yes*
Comments

6.3 An appropriate air exchange (e.g., ACPH) (minimum of 12 or 30 ACPH) [Table 2 & 3] *Yes*
Comments

6.4 A negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas *Yes*
Comments

7. Does the C-PEC operate continuously if it supplies some or all of the negative pressure in the C-SEC or if it is used for sterile compounding? *Yes*

USP 800 Section 5.3 Paragraph 3
Comments

8. Is a sink available for hand washing? *Yes*

USP 800 Section 5.3 Paragraph 4
Comments

9. Are water sources and drains located at least 1 meter from the C-PEC? *Not Inspected*

USP 800 Section 5.3 Paragraph 4
Comments

10. Are the C-PECs used for manipulation of nonsterile HDs either externally vented or have redundant-HEPA filters in series? *Yes*

USP 800 Section 5.3.1 Paragraph 2
Comments

11. Are the surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area smooth, impervious, free from cracks and crevices, and non-shedding? *Yes*

USP 800 Section 5.3.1 Paragraph 4
Comments

12. Does the facility utilize automated counting or packaging machines? *No*
12.1 Are automated counting or packaging machines not used by the facility for tablet and capsule forms of antineoplastic HDs?

USP 800 Section 12 Paragraph 2
Comments

13. Does the facility use the same C-PEC for sterile and nonsterile compounding?
13.1 Is the C-PEC is decontaminated, cleaned, and disinfected before resuming sterile compounding in that C-PEC?

USP 800 Section 5.3.1 Paragraph 2
Comments

14. Are all C-PECs used for manipulation of sterile HDs externally vented and provide an ISO Class 5 or better air quality? *Not Inspected*

USP 800 Section 5.3.2 Paragraph 2
Comments *No sterile compounding of HDs*

15. Are laminar airflow workbenches (LAFWs) or compounding aseptic isolators (CAIs) not used by the facility for the compounding of an antineoplastic HD? *Not Inspected*

USP 800 Section 5.3.2 Paragraph 3
Comments

16. Does the buffer room used for sterile compounding of HDs meet the following requirements?

USP 800 Section 5.3.2 Paragraph 5
16.1 ISO Class 7 buffer room *Not Inspected*
Comments *No sterile compounding of HDs*

16.2 Fixed walls *Not Inspected*
Comments *No sterile compounding of HDs*

16.3 HEPA-filtered supply air *Not Inspected*
Comments *No sterile compounding of HDs*

16.4 Negative pressure between 0.01 and 0.03 inches of water column *Not Inspected*
Comments *No sterile compounding of HDs*

16.5 A minimum of 30 ACPH *Not Inspected*
Comments *No sterile compounding of HDs*

17. Does the ante-room or non-HD buffer room servicing the HD buffer room used for sterile compounding meet the following requirements?:

USP 800 Section 5.3.2 Paragraph 6
Comments *No sterile compounding of HDs*

17.1 A minimum of 30 ACPH of HEPA-filtered supply air *Not Inspected*
Comments *No sterile compounding of HDs*

17.2 Positive pressure of at least 0.02 inches of water column *Not Inspected*
Comments *No sterile compounding of HDs*

17.3 ISO Class 7 or better *Not Inspected*
Comments *No sterile compounding of HDs*

17.4 A hand-washing sink placed in the ante-room at least 1 meter from the entrance to the HD buffer room *Not Inspected*

USP 800 Section 5.3.2 Paragraph 7
Comments *No sterile compounding of HDs*

18. Does the facility utilize a containment segregated compounding area (C-SCA) in an unclassified space for sterile HD compounding? *Not Inspected*
Comments *No sterile compounding of HDs*

19. Does the C-SCA meet the following?:
19.1 Fixed Walls

USP 800 Section 5.3.2 Paragraph 10
Comments

G. Standard Operating Procedures (SOPs)
1. Does the facility maintain SOPs for the handling of HDs? *Yes*

USP 800 Section 17 Paragraph 1
Comments

2. When was the last documented review date? *2025-03-01*

USP 800 Section 17 Paragraph 1
Comments

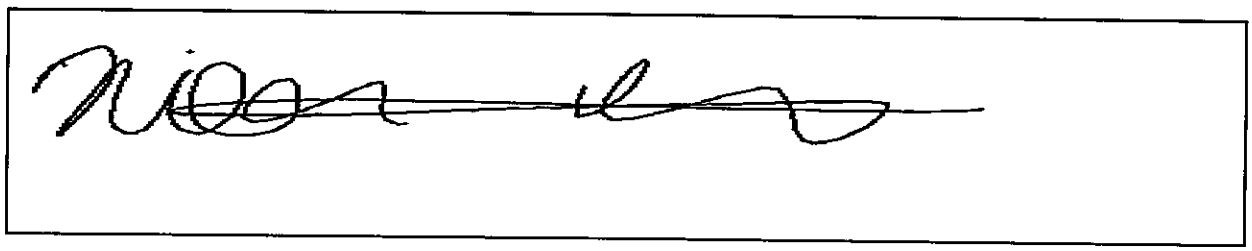
3. Is there documentation to demonstrate that the SOPs are reviewed by the designated person at least once every 12 months? *Yes*

USP 800 Section 17 Paragraph 1
Comments

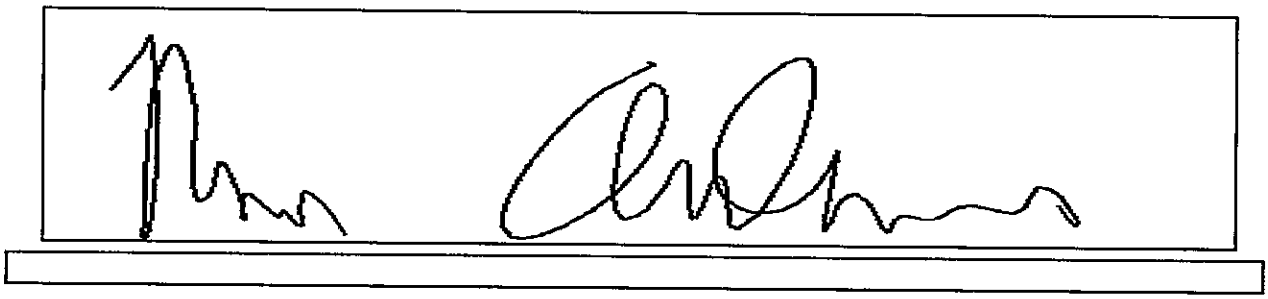
Notes *The facility does no sterile compounding of HDs. The facility primarily compounds hormone therapy products (creams/troche). The facility utilizes a negative-pressure room that contains 2 negative-pressure hoods. Will conduct a follow-up inspection in 30 days.*

This inspection report has been read and explained to the pharmacist whose name appears below. Explanations include any observed violations, deficiencies, or comments, and such are based on state/federal laws and rules pertaining to the practice of pharmacy in the State of Georgia. I do affirm the information I have given pursuant to this inspection is true and correct to the best of my knowledge. This inspection report is not intended to be all inclusive, and there may be deficiencies, non-compliance, or violations of the laws and rules not detected and noted in this report.

Facility Email: hiren@thepharmacyplace.com



Printed Name: Nilesh Patel
Inspection Date: August 11, 2025



Printed Name: Nick Aderibigbe, Special Agent, Georgia Drugs & Narcotics Agency
Inspection Date: August 11, 2025

19.2 Negative pressure between 0.01 and 0.03 inches of water column
Comments

19.3 A minimum of 12 ACPH
Comments

19.4 Externally vented
Comments

19.5 A hand-washing sink placed at least 1 meter from C-PEC and may be either inside the C-SCA or directly outside the C-SCA
Comments

F. Deactivating, Decontaminating, Cleaning, and Disinfecting/Spill Control
1. Are all areas where HDs handled and all reusable equipment and devices are deactivated, decontaminated, and cleaned? *Reviewed*

USP 800 Section 15 Paragraph 1
Comments

2. In addition, are all sterile compounding areas and devices subsequently disinfected? *Not Inspected*

USP 800 Section 15 Paragraph 1
Comments *No sterile compounding of HDs*

3. Is the work surface of the C-PEC decontaminated between compounding of different HDs, decontaminated at least daily (when used), any time a spill occurs, before and after certification, any time voluntary interruption occurs, and if the ventilation tool is moved? *Reviewed*

USP 800 Section 15.2 Paragraph 2
Comments

4. Are the areas under the work tray of the C-PEC deactivated, decontaminated, and cleaned at least monthly? *Reviewed*

USP 800 Section 15.2 Paragraph 3
Comments

5. Are spill kits with the materials needed to clean HD spills readily available in all areas where HDs are routinely handled? *Yes*

USP 800 Section 16 Paragraph 1
Comments

STATE OF GEORGIA
Georgia Board of Pharmacy
Retail Pharmacy
LICENSE NO. PHRE010257 Status: Active

The Pharmacy Place

2035 Commerce Drive North
Peachtree City GA 30269

Expires: 06/30/2027
Issued: 01/11/2016

Pharmacist in Charge RPH024644
Hiren K Patel

Real-time license verification is available at gadch.mylicense.com/verification

Above is your wall certificate license to practice as a **Retail Pharmacy** in the State of Georgia. A pocket-sized license card is below.

Please make note of the expiration date on your license. It is your responsibility to renew your license before it expires.
Please notify the Board if you have a change of address.

STATE OF GEORGIA
Georgia Board of Pharmacy
Retail Pharmacy
LICENSE NO. PHRE010257 Status: Active
The Pharmacy Place

2035 Commerce Drive North
Peachtree City GA 30269

Expires: 06/30/2027 Pharmacist in Charge RPH024644
Issued: 01/11/2016 Hiren K Patel
Real-time license verification is available at gadch.mylicense.com/verification

Licensee Information

Name:	The Pharmacy Place
Owner:	
DBA:	
Address:	2035 Commerce Drive North Peachtree City GA 30269

Primary Source License Information

Profession:	Pharmacy	**License No:**	PHRE010257	**License Status:**	Active
License Type:	Retail Pharmacy	**Obtained By Method:**	Transfer	**License Subtype:**	
Issue Date:	1/11/2016	**Expiration Date:**	6/30/2027	**Last Renewal Date:**	4/28/2025

Discipline Information
- Public Board Orders -

If a public board order exists, it may be listed below.
Public Board Order means that there is a public document concerning the licensee.
The existence of a public Board order does not necessarily mean the licensee is currently under any type of disciplinary action.

Please understand that the absence of a scanned order linked to this record does not necessarily mean that no public actions exist.

No scanned public board order documents exist.

Associated Licenses

Relationship:	Employment		
Prerequisite Licensee:	Mcelveen, Michael Thomas	**Prerequisite License:**	PHTC087933
Association Date:	6/8/2026	**Disassociation Date:**	
Relationship:	Employment		
Prerequisite Licensee:	Williams, Kyle Edward	**Prerequisite License:**	PHTC081328
Association Date:	3/17/2025	**Disassociation Date:**	
Relationship:	Supervisor		
Prerequisite Licensee:	Patel, Hiren K	**Prerequisite License:**	RPH024644
Association Date:	2/28/2025	**Disassociation Date:**	

You may close this window to return to your search results

Data current as of: June 8, 2026 16:2:37
This website is to be used as a primary source verification for licenses issued by the Boards of Dentistry and Pharmacy. Paper verifications are available for a fee. Please contact the Boards of Dentistry and Pharmacy at 404-651-8000.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: The Pharmacy Place

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): new app

Physical Address: 2035 Commerce Dr N

City: Peachtree City State: GA Zip: 30269

Mailing Address (if different from physical address): (same address)

City: State: Zip:

Telephone: 8335863111 Website: www.thepharmacyplace.com

Licensing Company Email: thepharmacyplacellc@gmail.com

Section 2: Personal Information

First: Hiren Middle: Last: Patel

Alias(es, nick[redacted] etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Peachtree city State: GA Zip: [redacted]

Telephon[redacted] Email[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
South University		08/05 - 05/08	
Address	**City**	**State**	**Zip**
709 Mall Blvd	Savannah	GA	31406
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
GA State University		08/02 - 05/05	
Address	**City**	**State**	**Zip**
100 Auburn Ave	Atlanta	GA	30303
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Clayton High School		08/98 - 05/02	
Address	**City**	**State**	**Zip**
600 Merlin Street	Clayton	GA	30417
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/11 - Current	[redacted]	Peachtree City	GA	[redacted]
04/09 - 12/11	[redacted]	Peachtree City	GA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
The Pharmacy Place			04/16 – Current	
Business Address		**City**	**State**	**Zip**
2025 Commerce Dr N		Peachtree City	GA	30269
Phone	**Title**			
678-271-2970	Pharmacist / Owner			
Description of Duties				
Pharmacy Manager				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7/4/2016
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hiten Patel

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/15/2026

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/15/2026

Date

Subscribed and Sworn to before me this 15th day of July.

Mara Rachel Bogdanski

Notary Public Signature

MARA RACHEL BOGDANSKI NOTARY PUBLIC FAYETTE COUNTY, GA Exp. 11/3/2029 (Seal)

400

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 02178	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Specialty Pharmacy	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: [redacted] ☒ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Amber Enterprises, Inc. d/b/a Amber Specialty Pharmacy

Physical Address: 10004 S. 152nd St., Suite A

City: Omaha State: NE Zip: 68138

Mailing Address (if different from physical address): [Same as physical address]

City: _____ State: _____ Zip: _____

Telephone: 402-896-5000 Toll Free # (NAC 639.708, NRS 639.23286): 888-370-1724

Fax: 402-896-3774 Contact Email: licensure@amberpharmacy.com

Website: www.amberpharmacy.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Pamela Helser

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21225

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Pamela Helser	NV Pharmacist Registration #: 21225
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nebraska

Parent Company (if any): CenterWell Pharmacy, Inc.

Corporation/Organization Name: Amber Enterprises, Inc. d/b/a Amber Specialty Pharmacy

Mailing Address: 10004 S. 152nd St., Suite A

City: Omaha State: NE Zip: 68138

Telephone: 402-896-5000 Email: licensure@amberpharmacy.com

Contact Person Name: Tanisha Curtis

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Amber Enterprises, Inc. d/b/a Amber Specialty Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Bethanie Stein

Print Name of Authorized Person

Bethanie J Stein

Original signature of Authorized Person (copies or stamps not accepted)

7-13-26

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Bethanie Stein hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for Amber Enterprises, Inc. d/b/a Amber Specialty Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Bethanie J Stein
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 13th day of July, 2026

Caitlin Vanover
Notary Public

Caitlin Rae Vanover
Notary Public, ID KYNP70542
State at Large, Kentucky
My Commission Expires on April 13, 2027

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bethanie Stein

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Bethanie J Stein

Original signature of Authorized Person (copies or stamps not accepted)

7-13-26

Date

Board Use Only	Date Received: 7/27/26	Amount: $500 ck 9611 10

Amber Enterprises, Inc. dba Amber Specialty Pharmacy

Discipline Explanation

Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?

Omaha, NE – Pharmacy Discipline

Colorado, 2010. The Colorado Board of Pharmacy alleged that the pharmacy failed to submit required data to Colorado's Prescription Drug Monitoring Program. The Board's Stipulation and Final Agency Order imposed a fine in the amount of $5,000 with a surcharge in the amount of $500, which the pharmacy paid. The out-of-state prescription drug outlet license is currently active and in good standing.

Texas, 2016. The Texas Board of Pharmacy notified the pharmacy that it intended to take disciplinary action based on allegations that the pharmacy failed to disclose the Colorado Board of Pharmacy Stipulation and Final Agency Order on its initial non-resident pharmacy license application submitted to the Texas Board of Pharmacy in 2013. The pharmacy signed an Agreed Board Order, pursuant to which the pharmacy paid an administrative penalty in the amount of $1,000. The non-resident pharmacy license is currently active and in good standing.

Hawaii, 2019. The Hawaii Board of Pharmacy alleged that the pharmacy failed to timely report the Texas Board of Pharmacy Agreed Board Order and south to imposed reciprocal discipline based on the Texas Board of Pharmacy Agreed Board Order. The pharmacy and the Board entered a Settlement Agreement, pursuant to which the pharmacy paid $300. The pharmacy permit is currently active and in good standing.

Maine, 2022. The pharmacy failed to notify the Board of a change in pharmacist-in-charge within seven days of the effective date of the change. The pharmacy notified the Board within thirteen days of the effective date of the change. As this was a first-time violation of the notification requirement, the pharmacy, the Board and the Maine Attorney General entered a Consent Agreement, under which the pharmacy received a warning and a civil penalty in the amount of $250, which it paid. The mail order pharmacy license is currently active and in good standing.

Ambler, PA (Not licensed in Nevada) – Pharmacy Discipline

Pennsylvania, 2012. The Pennsylvania Board of Pharmacy alleged that the pharmacy failed to notify the Board of a change in pharmacy management within fifteen (15) days of the date the change took effect. The Board issued a citation requiring the payment of a $400 fine.

CenterWell Pharmacy

Summary of Actions

Maine Board of Pharmacy Complaint 2008-PHA-4787
In 2008, CenterWell Pharmacy, Inc. (formerly Humana Pharmacy, Inc.) located at 4302 W. Buckeye Rd., Phoenix, AZ 85043 admitted to a violation as a result of a complaint 2008-PHA-4787 where a prescription order was shipped to a patient who did not order the medication. There was no ingestion of the medication, and no patient harm. The root cause of the issue was Human Error. The Maine Board of Pharmacy offered a Consent Agreement where there was an admitted violation, a warning from the Board, and a $100 fine. This Agreement was previously reported to the Board.

Colorado Department of Commerce and Consumer Affair's Regulated Industries Complaints Office
CenterWell Pharmacy, Inc. (formerly Humana Pharmacy, Inc.) located at 4302 W. Buckeye Rd., Phoenix, AZ 85043 entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy on 5/19/2011. CenterWell Pharmacy, Inc. admitted to a violation of Board Rule 5.00.70 in which the pharmacy failed to timely submit the required applications and fees to the Colorado Board detailing a change in Pharmacist Managers. The violation was unintentional and root cause of the error was investigated and found to be an administrative error. The error was corrected, and imposed fees were paid. This Order was previously reported to the Board.

Hawaii Board of Pharmacy (PHA 2011-21-L and PHA 2010-32-L)
In December 2008, CenterWell Pharmacy, Inc. (formerly Humana Pharmacy, Inc.) located at 4302 W. Buckeye Rd., Phoenix, AZ 85043 entered into a Consent Agreement with the Maine Board of Pharmacy. Per Hawaii Revised Statutes, disciplinary decisions must be reported within 30 days. It is important to note that Humana Pharmacy, Inc. did notify the Hawaii Board of Pharmacy of the Consent Agreement. However, the notification exceeded the timeframe required by HRS 436B-19(15). PHA 2011-21-L is due to CenterWell Pharmacy, Inc. (formerly Humana Pharmacy, Inc.) receiving disciplinary action by another state agency. These agreements were previously reported to the Board.

Iowa Board of Pharmacy
CenterWell Pharmacy, Inc. (formerly Humana Pharmacy, Inc.) located at 4302 W. Buckeye Rd., Phoenix, AZ 85043 entered into a Settlement Agreement and Final Order with the Iowa Board of Pharmacy in August 2013. Pursuant to this Settlement Agreement and Final Order,

the Iowa Board of Pharmacy cited CenterWell Pharmacy, Inc. for having disciplinary action taken against it by another state licensing board. This action taken by the Iowa Board of Pharmacy is based entirely on the Settlement Agreement with the Hawaii Board of Pharmacy, and no new violations occurred. The Agreement was previously reported to the Board.

Michigan Board of Pharmacy
CenterWell Pharmacy, Inc. (formerly Humana Pharmacy, Inc.) located at 4302 W. Buckeye Rd., Phoenix, AZ 85043 entered into a Consent Order and Stipulation with the Michigan Department of Licensing and Regulatory Affairs which was received by CenterWell Pharmacy, Inc. in April 2014. The Administrative Complaint resulting in the Consent Order is in response to CenterWell Pharmacy, Inc. having violated section 17768(2) (d) of the Public Health Code due to receiving disciplinary action by other Regulatory Agencies. The Consent Order is based entirely on previously reported Settlement Agreements, and no new violations have occurred. The Order was previously reported to the Board.

Alaska Board of Pharmacy
CenterWell Pharmacy, Inc. (formerly Humana Pharmacy, Inc.) located at 4302 W. Buckeye Rd., Phoenix, AZ 85043 accepted an Imposition of Civil Fine without reprimand from the Alaska Board of Pharmacy in August 2014 due to a misinterpretation of a question on a 2010 renewal application. CenterWell Pharmacy, Inc. did not intentionally answer the question incorrectly, and it was answered based off of the interpretation of the question at that time. The action was previously reported to the Board.

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2010-003228

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF THE DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION OF AMBER PHARMACY, REGISTRATION NO. OSP 5583,

RESPONDENT PHARMACY.

IT IS HEREBY STIPULATED by and between the Colorado State Board of Pharmacy ("Board") and Amber Pharmacy ("Respondent Pharmacy"), to resolve all matters pertaining to Board Case Number 2010-003228 as follows:

1. The Board has jurisdiction over Respondent Pharmacy, its registration as a non-resident prescription drug outlet, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of title 12, article 22, C.R.S. (2009), otherwise known as the Pharmaceuticals and Pharmacists Act.

2. Respondent Pharmacy has been registered by the Board as a non-resident prescription drug outlet in the State of Colorado at all times relevant to this disciplinary action.

3. Respondent Pharmacy's address of record with the Board and current location is 10004 S. 152nd St., Ste. A, Omaha, NE 68138. Respondent Pharmacy is an operating division of Amber Enterprises Inc., a Nebraska corporation.

4. Respondent Pharmacy neither admits nor denies these findings but does not contest that the Board alleges these findings. It hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Pharmacy failed to submit required data into Colorado's Prescription Drug Monitoring Program (PDMP) for the February 16, 2010, through February 25, 2010, reporting period.

6. On March 8, 2010, the Board initiated a complaint against Respondent Pharmacy because Respondent Pharmacy failed to comply with the data submission requirements of the PDMP.

7. Respondent Pharmacy does not contest that the conduct described above constitutes a violation of section 12-22-125(1)(c)(I), (II) and (III) and 12-22-708,

C.R.S., and that such conduct provides grounds for disciplinary action against Respondent Pharmacy's non-resident prescription drug outlet registration.

DISPOSITION

$5,000.00 Fine with Surcharge and Terms

8. **Fine with Surcharge.** Pursuant to section 12-22-125.2(5), C.R.S., Respondent Pharmacy shall pay a fine of Five Thousand Dollars and No Cents ($5,000.00). Respondent Pharmacy understands and acknowledges that, pursuant to section 24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 10% of this fine. Respondent Pharmacy shall therefore pay a total amount of Five Thousand, Five Hundred Dollars and No Cents ($5,500.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Pharmacy submits this signed Final Agency Order to the Board.

9. **Compliance.** Respondent Pharmacy shall at all times comply with the data submission requirements of the PDMP.

10. **Advisements and Waivers.** Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, whether or not Respondent Pharmacy has consulted with legal counsel. Respondent Pharmacy acknowledges its understanding that it has the following rights:

    a. To have a formal notice of hearing and charges served upon it;
    b. To respond to said formal notice of charges;
    c. To have a formal disciplinary hearing pursuant to section 12-22-125, C.R.S.; and
    d. To appeal this Board order.

    Respondent Pharmacy freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

11. **Acknowledgments.** The undersigned authorized agent of Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, whether or not Respondent Pharmacy has consulted with legal counsel, that Respondent Pharmacy understands the legal consequences and agrees that none of the terms or conditions herein are unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.

12. **Violations.** Time is of the essence to this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully

with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order may be sanctioned as provided under section 12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.

13. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties in this case. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

14. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

15. **Effective Date.** This Final Agency Order shall become effective upon signature of a Board member or representative.

ACCEPTED AND AGREED BY

[signature]
Authorized Agent of Respondent Pharmacy

Dated: 07-20-2010

Subscribed and sworn to before me in the County of Sarpy, State of Nebraska, this 20 day of July, 2010 by William Kaplan Jr, in his/her capacity as an authorized agent of Amber Pharmacy.

GENERAL NOTARY-State of Nebraska
SUSAN K. LANGENFELD
My Comm. Exp. Dec 13, 2010

[signature]
Notary Public

My commission expires: Dec. 13, 2010

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

DONE AND EFFECTIVE THIS 4th DAY OF August, 2010.

State Board of Pharmacy

BY: Wendy Anderson
Wendy Anderson
Program Director

AGREED BOARD ORDER #F-17-003

RE: IN THE MATTER OF
AMBER PHARMACY
(PHARMACY LICENSE #28790)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 28790 issued to Amber Pharmacy (Respondent), 10004 South 152nd Street, Suite A, Omaha, Nebraska 68138.

By letter dated November 17, 2016, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

Sections 565.002(a)(3), (10) and (13); and 565.002(c) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2011); and

Section 281.8(c)(3) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2013), in that allegedly:

COUNT

On or about August 4, 2010, the Colorado State Board of Pharmacy entered a Stipulation and Final Agency Order against the non-resident prescription drug outlet registration OSP 5583 held by Amber Pharmacy. The Order was based on allegations that Amber Pharmacy failed to submit required data into Colorado's Prescription Drug Monitoring Program for a period of nine days in February 2010. The Order imposed a $5,000 fine.

On or about April 1, 2013, Amber Pharmacy submitted to the Texas State Board of Pharmacy an application for initial licensure as a nonresident pharmacy. On the application, it was falsely indicated that the pharmacy had not been the subject of professional disciplinary action by any regulatory authority, when the pharmacy was disciplined by the Colorado State Board of Pharmacy in 2010, as previously described.

By letter dated November 17, 2016, Respondent was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By signing this Order, Aaron Wiese, President, Amber Pharmacy, on behalf of Respondent, neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to informal conference, notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent shall pay an administrative penalty of one thousand dollars ($1,000) due one hundred twenty (120) days after the entry of this Order.

(2) Respondent shall allow Board staff to directly contact Respondent on any matter regarding the enforcement of this Order.

(3) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2015), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2016).

And it is so Ordered.

THIS ORDER IS A PUBLIC RECORD.

Signed and entered by the Executive Director on behalf of the Texas State Board of Pharmacy on this 15th day of December, 2016.

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Aaron Wiese, President, Amber Pharmacy
For and on behalf of Amber Pharmacy

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel
Texas State Board of Pharmacy

STACIA M. SILVA 6760
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: (808) 586-2660

Attorney for Department of Commerce
and Consumer Affairs

DEPT. OF COMMERCE AND CONSUMER AFFAIRS
2019 JUN 21 P 12:23
HEARINGS OFFICE

RECEIVED
PROF & VOCATIONAL LICENSING DIV
2019 MAY 29 A 9:59
DEPT OF COMMERCE & CONSUMER AFFAIRS

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of AMBER ENTERPRISES, INC., doing business as AMBER PHARMACY, Respondent.	PHA 2018-50-L SETTLEMENT AGREEMENT AFTER FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

SETTLEMENT AGREEMENT AFTER FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorney(s), and Respondent AMBER ENTERPRISES, INC., doing business as AMBER PHARMACY (hereinafter "Respondent") enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was permitted by the Board of Pharmacy (hereinafter the "Board") as a miscellaneous permit holder under permit number PMP 1003. The permit was issued on or about June 5, 2014, and has an expiration date of December 31, 2019.

2. Respondent's mailing address for purposes of this action is c/o Joseph M. Acierno, M.D., J.D., Amber Enterprises, Inc., dba Amber Pharmacy, 10004 South 152nd Street, Suite A, Omaha, Nebraska 68138.

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.
2239

3. On or about February 26, 2019, RICO filed a Petition for Disciplinary Action (hereinafter "Petition") alleging that Respondent violated, in part, the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") §§ 436B-19(13) (revocation suspension, or other disciplinary action by another state or federal agency against a licensee or applicant for any reason provided by the licensing laws or this section), and 436B-19(15) (failure to report in writing any disciplinary decision within thirty days of the decision).

4. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is represented by Joseph M. Acierno, M.D., J.D., Amber Enterprises, Inc., dba Amber Pharmacy, 10004 South 152nd Street, Suite A, Omaha, Nebraska 68138.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent, being at all times relevant herein permitted as a miscellaneous permit holder by the Board, acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent does not admit to violating any law or rule.

6. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

7. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2018-50-L and the permit identified in this Settlement Agreement.

8. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

C. TERMS OF SETTLEMENT:

1. Administrative Fine. Respondent agrees to pay a fine in the amount of THREE HUNDRED AND NO/100 U.S. DOLLARS ($300.00). Payment shall be due upon the return of this executed document to RICO. Said payment shall be made by **cashier's check or money order made payable to "State of Hawaii - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn.: Stacia M. Silva, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph C.1 above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the permit to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands that Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of miscellaneous permit holders in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5, C.6, C.7 and C.8 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that they nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof, contains the entire agreement of the parties, and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: Honolulu (CITY), HI (STATE), May 15, 2019 (DATE)

AMBER ENTERPRISES, INC., doing business as AMBER PHARMACY
Respondent

By: _____ (Signature)
Adam L. Jhee (Print Name)
Its President

DATED: Honolulu, Hawaii, MAY 23 2019

_____
STACIA M. SILVA
Attorney for Department of Commerce and Consumer Affairs

APPROVED AS TO FORM:

_____
JOSEPH M. ACIERNO, M.D., J.D.
Attorney for Respondent

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF AMBER ENTERPRISES, INC., DOING BUSINESS AS AMBER PHARMACY; SETTLEMENT AGREEMENT AFTER FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; RICO CASE NO. PHA 2018-50-L

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

KERRI OKAMURA SHERI TOKUMARU
Chairperson

June 20, 2019
DATE

JULIE YURIE TAKISHIMA-LACASA
Vice Chair

MARY JO KEEFE

CAROLYN S. J. MA

ALANNA ISOBE

RONALD WEINBERG

KENNETH VANDENBUSSCHE

PVL 08/2018

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
AMBER ENTERPRISES, INC.	)	
	)	CONSENT AGREEMENT
Case No. 2022-PHA-18210	)	

PARTIES

This document is a Consent Agreement regarding disciplinary action against the mail order prescription pharmacy license of Amber Enterprises, Inc. d/b/a Amber Specialty Pharmacy ("Amber") in the State of Maine. The parties to this Consent Agreement are: Amber, the Maine Board of Pharmacy ("the Board"), and the Maine Office of the Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

FACTS

1. At all times relevant to this matter, Amber was licensed by the Board as a mail order prescription pharmacy, license no. MO40001367, located at 10004 S 152nd Street, Suite A, Omaha, Nebraska.

2. On January 1, 2021, Amy N. Adams replaced Kelli M. Wyant as the pharmacist in charge ("PIC") of Amber, thereby requiring Amber to submit a change of PIC application to the Board within 7 days after the PIC change.

3. Amber, however, did not file a change of PIC application with the Board until January 13, 2021.

4. On April 5, 2022, Board Administrator, Geraldine Betts, filed an administrative complaint with the Board alleging that Amber had failed to file a timely change of PIC application.

5. This administrative complaint was docketed as Case No. 2022-PHA-18210.

6. Under Board Rules Chapter 11, § 3, upon a change of PIC, a mail order prescription pharmacy must file a new application with the Board by registered mail no later than seven (7) days after the change.

7. Pursuant to the Board's delegation of authority dated November 9, 2020, which authorizes Board Staff to offer prescribed consent agreements to resolve first-time violations of PIC change notification requirements, this Consent Agreement is being offered to finally resolve Case No. 2022-PHA-18210.

8. Absent acceptance of this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Complaints Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333-0035 by **August 31, 2022,** the Board will resolve this matter by holding an adjudicatory hearing.

COVENANTS

9. Amber admits to the facts as stated above and admits that such conduct constitutes grounds for discipline pursuant to 10 M.R.S. § 8003(5-A)(A)(5) for violating a rule of the Board, specifically Board Rules Chapter 11, § 3, by failing to file a new application with the Board by registered mail no later than 7 days after a change of PIC.

10. As DISCIPLINE for the violation admitted to in paragraph 9 above, Amber agrees to accept the imposition of:

a. A WARNING; and

b. A CIVIL PENALTY in the amount of two hundred fifty dollars ($250.00). Payment of the civil penalty shall be made by check or money order payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35

State House Station, Augusta, Maine 04333, and must be submitted with the signed Consent Agreement.

11. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

12. Violation of any of the terms or conditions of this Consent Agreement by Amber shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

13. The Board and the Office of the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

14. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

15. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

16. The Board and Amber agree that no further agency action will be initiated against Amber's license by the Board based upon the specific violations admitted to herein, except or unless Amber fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct in the event that other allegations are brought against Amber, and this Consent Agreement will be introduced as evidence in any future adjudicatory hearing involving Amber. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining discipline in any further complaints against Amber.

17. Amber acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it

executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

Amber Enterprises, Inc.

DATED: 8/29/22

BY: [signature]
Authorized Representative

Kristin Williams
Printed Name

DATED: 8-30-22

[signature]
EDWARD KANE, President
Maine Board of Pharmacy

DATED: 8.31-22

[signature]
JENNIFER A. WILLIS
Assistant Attorney General

Commonwealth of Pennsylvania
DEPARTMENT OF STATE
HARRISBURG, PA 17105

CITATION

CITATION NO.
50242

1. RESPONDENT Amber Pharmacy				2. FILE NO. 12-54-00242
3. SEX N/A	4. D.O.B N/A		5. AGE N/A	6. LICENSE NO. PP481535
7. RECORD ADDRESS 323 Norristown Road Suite 100	CITY Ambler		STATE PA	ZIP CODE 19002

2012 JUN -8 PM 3:12
Department of State

8. CHARGE
failing to notify the Board of a change in pharmacy management within fifteen (15) days of the date the change took effect

9. STATUTE OR REGULATION VIOLATED		10. FACILITY ADDRESS
Violation #1. 49 Pa. Code § 27.11(g)	FINE $400.00	Amber Pharmacy Attention : Josephine M. Fields, R.Ph. 323 Norristown Road Suite 100 Ambler, PA 19002
Violation #2.	FINE	
Violation #3.	FINE	
11. TOTAL DUE	$400.00	

12. SEND PAYMENT TO:
PA. DEPARTMENT OF STATE
ATTN: PROFESSIONAL COMPLIANCE OFFICE – CITATIONS
PO BOX 2649
HARRISBURG PA 17105

13. RECEIPT OF CITATION ACKNOWLEDGED – SIGNATURE	14. DATE ISSUED
	May 14, 2012

I Verify That The Facts Set Forth In This Citation Are True And Correct To The Best Of My Knowledge Or Information And Belief. This Verification Is Made Subject To The Penalties Of Section 4804 Of The Crimes Code (18 Pa.C.S. § 4804) Relating To Unsworn Falsification To Authorities.

15. ISSUER SIGNATURE	16. ID NO.	17. REGION
María Rosa Consuelo Tolentino		Harrisburg

18. REMARKS
Respondent Pharmacy's management changed on or about April 24, 2011; however, the Board did not approve the change due to discrepancies until the proper applications were filed on or about November 17, 2011. This Citation is being served by certified mail, return receipt requested and first class mail. If Ms. Fields is not available to sign the return receipt, an employee or any other representative of the Respondent Pharmacy may sign the receipt on its behalf.

READ THE NOTICE OF RIGHTS AND OBLIGATIONS ON THIS CITATION FOR AN EXPLANATION OF YOUR RIGHTS AND OBLIGATIONS FOR SETTLEMENT OF THIS MATTER. YOU ***MUST*** ELECT ONE OF THE PLEA OPTIONS AND FOLLOW THE APPROPRIATE DIRECTIONS WITHIN 10 DAYS TO AVOID FURTHER LEGAL ACTION AGAINST YOUR LICENSE.

SHOULD YOU ELECT TO DEMAND A HEARING ON THIS MATTER, FOLLOW THESE INSTRUCTIONS CAREFULLY. YOUR HEARING DATE WILL BE ON

August 14, 2012 AT 9:00 A.M.

ALL HEARINGS ARE HELD IN HARRISBURG IN THE OFFICE OF HEARING EXAMINERS, 2601 NORTH THIRD STREET, HARRISBURG, PA 17105

PLEASE PLACE THE CITATION NUMBER(S) ON YOUR CERTIFIED OR CASHIER'S CHECK OR MONEY ORDER

PERSONAL CHECKS WILL NOT BE ACCEPTED

NOTICE OF RIGHTS AND OBLIGATIONS

The original of this citation will be filed with the Professional Compliance Office of the Bureau of Professional and Occupational Affairs at the address listed herein. You should receive this citation by certified mail and by first class mail. Please respond only once.

YOU HAVE THE RIGHT TO HAVE AN INTERPRETER AT YOUR HEARING. YOU MUST NOTIFY US OF THIS REQUEST WHEN YOU RETURN YOUR PLEA.

WITHIN TEN (10) DAYS OF THE RECEIPT OF THIS CITATION, YOU MUST:

–ADMIT TO THE VIOLATION(S) by signing the appropriate plea below and mailing the entire RESPONDENT'S RETURN copy of this Citation along with an amount equal to the Total Due as specified in Box 11 to the Professional Compliance Office at the address listed in Box 12.

–DENY THE VIOLATION(S) by signing the appropriate plea below and mailing the entire RESPONDENT'S RETURN copy of this Citation to the Professional Compliance Office at the address in Box 12. If you deny the violation(s), a formal hearing will be scheduled in Harrisburg at which you may present evidence on your behalf. Failure to appear at the formal hearing will result in the entry of a default judgment against you for the full amount of the Civil Penalty ("Total Due") as specified in Box 11 of this Citation.

All payments must be made by certified or cashier's check or money order and made payable to the "Commonwealth of Pennsylvania," and mailed to the address on the reverse side. Please place the Citation Number on your certified or cashier's check or money order. PERSONAL CHECKS WILL NOT BE ACCEPTED.

SUBMISSION OF PAYMENT CONSTITUTES AN ADMISSION OF THE VIOLATION

Failure to respond within the time specified above will result in the entry of a default judgment against you for the full amount of the Civil Penalty ("Total Due") as specified on this Citation. Failure to pay a civil penalty could result in additional fines and the revocation, suspension or other disciplinary action against any license which you may hold.

PLEA

Place the RESPONDENT'S RETURN copy of the Citation and your certified or cashier's check or money order in an envelope and mail to the address listed in Box 12.

I understand this notice of my rights and obligations. Further, I represent that I make this plea knowingly, voluntarily and intelligently. I understand that false statements herein are made subject to the Criminal Penalties of 18 Pa. C.S. §4904 relating to unsworn falsification to authorities. Failure to indicate a plea when forwarding an amount equal to the Total Due as specified on this Citation will result in a plea admitting to all violations being recorded.

1. I ADMIT to the violation(s) on this Citation

Signature _____ Date 5/23/12

2. I DENY the violation(s) on this Citation

Signature _____ Date _____

RESPONDENT COPY
CERTIFIED MAIL

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
HUMANA PHARMACY, INC.	)	CONSENT AGREEMENT
	)	
Complaint No. 2008-PHA-4787	)	

PARTIES

This document is a Consent Agreement regarding disciplinary action against Humana Pharmacy Inc.'s license to operate a mail order prescription pharmacy dispensing prescription drugs to patients residing in the State of Maine. The parties to this Consent Agreement are: Humana Pharmacy, Inc. ("Humana") with a principal place of business in Phoenix, Arizona, the State of Maine Board of Pharmacy ("the Board") and the Maine Office of the Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

FACTS

1. At all times pertinent to this matter, Humana was licensed by the Board to operate a mail order prescription pharmacy in Phoenix, Arizona dispensing prescription drugs to patients residing in Maine, license number MO40000472.
2. On or about July 10, 2008, the Board received a complaint against Humana pertaining to an alleged prescription order that was improperly sent to a consumer in Maine.
3. The Board docketed the complaint as Complaint No. 2008-PHA-4787.
4. The complaint alleges that on or about June 26, 2008, Humana sent a consumer residing in Maine prescription drugs that the consumer did not order.

5. The drug container was labeled by Humana with the name of the Maine resident and indicated that the prescribing practitioner was a physician from Florida.
6. Humana charged the cost of the drugs to the credit card of the Maine consumer and to Medicare.
7. On November 18, 2008, following a presentation of the complaint, the Board voted to offer Humana this Consent Agreement, in order to resolve Complaint No. 2008-PHA-4787. Absent acceptance of this Consent Agreement by signing and dating it and returning it to Kelly McLaughlin, Board Clerk, Board of Pharmacy, 35 State House Station, Augusta, Maine 04333-0035 by January 5, 2009, the Board will resolve this matter by holding an adjudicatory hearing.

COVENANTS

8. Humana admits that it was responsible for dispensing the erroneously filled prescription as described in paragraphs 4 through 6 above and admits that such conduct constitutes grounds for disciplining it pursuant to 10 M.R.S. § 8003(5-A)(A)(5), for violating a rule of the Board as follows:
    a. Chapter 30 § 15 by failing to establish and maintain effective controls to prevent prescription errors or misfills; and
    b. Chapter 30 § 16 by failing to address or attempt to resolve a possible prescription error which was apparent or should have been apparent.

9. As DISCIPLINE for the conduct admitted in paragraph 8 above, Humana agrees to

   a. Accept a WARNING; and

   b. Pay a CIVIL PENALTY in the amount of one hundred dollars ($100.00), which shall be made by check or money order payable to the "Treasurer, State of Maine" and delivered to Kelly McLaughlin, Board Clerk, Board of Pharmacy, 35 State House Station, Augusta, Maine 04333-0035, within thirty (30) days of the execution of this Consent Agreement.

10. Violation of any of the terms or conditions of this Consent Agreement by Humana shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

11. This Consent Agreement is not appealable and is effective until modified or rescinded by the parties hereto.

12. The Board and the Office of the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

13. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408.

14. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

15. Humana acknowledges by signature of an authorized representative hereto that it has read this Consent Agreement, that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executed this Consent Agreement of its own free will, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 12/18/08

For HUMANA PHARMACY, INC.

Dennis K. McAllister, Pharmacist in charge
Print Name and Title

DATED: 12/31/08

LORI A. McKEOWN, R.Ph., President
Maine Board of Pharmacy

DATED: 12/29/2008

ANDREW L. BLACK
Assistant Attorney General

BEFORE THE STATE BOARD OF PHARMACY
STATE OF COLORADO

Case Nos. 2011-1151 and 2011-1153

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION OF **HUMANA PHARMACY, INC.**, REGISTRATION NO. OSP 5672,

Respondent Pharmacy.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Humana Pharmacy, Inc. ("Respondent Pharmacy") to resolve all matters pertaining to Board Case Numbers 2011-1151 and 2011-1153, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Pharmacy, its registration as a non-resident prescription drug outlet, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S. (2010).

2. Respondent Pharmacy was originally registered as an non-resident prescription drug outlet in the State of Colorado on November 7, 2006, being issued registration number OSP 5672, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Pharmacy admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

4. Respondent Pharmacy's address of record with the Board and current location is 4302 West Buckeye Road, Phoenix, Arizona 85043.

5. On two separate occasions, Respondent Pharmacy failed to timely submit the required applications and fees to the Board detailing changes in pharmacist managers. In Board Case No. 2011-1151, a new pharmacist manager sent a letter to the Board on June 2, 2008 informing it that he had taken over as the new pharmacist manager, and asking if there was "anying further" required of him. However, the required application and fee were never submitted detailing him as the pharmacist manager during the 562-day time period that pharmacist served as manager between May 12, 2008 and February 1, 2010. In Board Case No. 2011-1153, 198 days elapsed during which time he served as interim pharmacist manager between February 1, 2010 and August 19, 2010 when the application and fee were received detailing him as the new pharmacist manager.

6. Respondent Pharmacy's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drugs.

12-22-130. Nonresident prescription drug outlet - registration.

(4) (a) The board may deny, revoke, or suspend a nonresident prescription drug outlet registration for failure to comply with any provision of this section or with any reasonable rule promulgated by the board.

* * *

Pharmacy Board Rules

5.00.70 Change in Pharmacist Manager.

b. The registration of any in-state and non-resident prescription drug outlet shall become void if the pharmacist manager in whose name the registration was issued ceases to be engaged as the manager, and the owner shall close the outlet unless such owner has employed a pharmacist manager and, within fourteen days after termination of the former manager's employment, has made application to transfer the registration to the new pharmacist manager and has paid the transfer fee therefor.

* * *

7. The Board finds and concludes, and Respondent Pharmacy agrees, that based upon Respondent Pharmacy's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

TERMS OF DISCIPLINE

8. **Fine with Surcharge.** Pursuant to §12-22-125.2(5), C.R.S., Respondent Pharmacy shall pay a fine of Five Thousand Dollars and No Cents ($5,000.00). Respondent Pharmacy understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 10% of this fine. Respondent Pharmacy shall therefore pay a total amount of Five Thousand Five Hundred Dollars and No Cents ($5,500.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Pharmacy submits this signed Final Agency Order to the Board.

9. **Compliance.** Respondent Pharmacy shall submit all future applications, on the form prescribed by the Board, to the Board detailing changes in pharmacist manager and fees within fourteen (14) days of the previous pharmacist manager ceasing the position.

10. **Other Requirements.** Respondent Pharmacy acknowledges and agrees that, as a condition of this Final Agency Order and probation, it shall:

    a. promptly pay all its own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. **Advisements and Waivers.** Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, after having consulted with legal counsel. Respondent Pharmacy acknowledges its understanding that it has the following rights:

    a. to have formal notice of hearing and charges served upon it;

    b. to respond to said formal notice of charges;

    c. to have a formal disciplinary hearing pursuant to Sections 12-22-125 and 12-22-125.2(2)(a), C.R.S.; and

    d. to appeal this Final Agency Order.

    Respondent Pharmacy freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Pharmacy to the sanctions imposed herein.

12. **Acknowledgments.** Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, after having consulted with legal counsel, that Respondent Pharmacy

understands its legal consequences and agrees that none of its terms or conditions is unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.

13. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Pharmacy's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.

14. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

15. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

Effective Date. This Final Agency Order shall become effective upon signature by a Board representative.

ACCEPTED AND AGREED BY

Respondent Pharmacy

William Fleming / VP
Authorized Representative / Title

Dated: 5/9/11

Subscribed and sworn to before me in the County of Jefferson, State of Kentucky, this 9 day of May, 2011 by William Fleming thorized representative of Humana Pharmacy, Inc.

My commission expires: 2/8/2015

Carol Keinsley
Notary Public

CAROL KEINSLEY
Notary Public
State at Large
Kentucky
My Commission Expires Feb 8, 2015

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 19th day of May, 2011.

State Board of Pharmacy

BY: Wendy Anderson
Wendy Anderson
Program Director

DOCUMENT APPROVED AS TO FORM

QUARLES & BRADY LLP

CHRISTINE CASSETTA*

Attorneys for Respondent Pharmacy

One Renaissance Square
Phoenix, Arizona 85004-2391
Telephone: (602) 229-5258
FAX: (602) 420-5036
christine.cassetta@quarles.com
*Counsel of Record

JOHN W. SUTHERS
Attorney General

JOANNA LEE KAYE, #20486*
Assistant Attorney General
Business and Licensing Section

Attorneys for State Board of Pharmacy

1525 Sherman Street, 5th Floor
Denver, Colorado 80203
Telephone: (303) 866-6170
FAX: (303) 866-5395
jo.kaye@state.co.us
*Counsel of Record

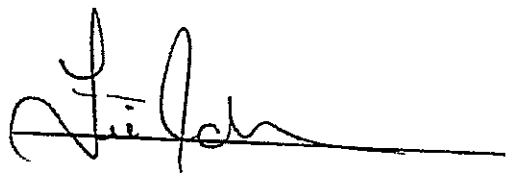
CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 19th day of May 2011, addressed as follows:

Christine Cassetta, Esq.
Quarles & Brady LLP
One Renaissance Square
Phoenix, Arizona 85004-2391

and via interagency mail to:

Jo Kaye
Assistant Attorney General



RECEIVED
PROFESSIONAL
2012 OCT 11 P 1:37
DEPT OF COMMERCE
STATE OF HAWAII

DENISE P. BALANAY 5526
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorney for Department of Commerce
and Consumer Affairs

RECEIVED
2012 DEC 20 P 1:19
DEPT OF COMMERCE AND CONSUMER AFFAIRS

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of HUMANA PHARMACY, INC., doing business as RIGHTSOURCE, Respondent.	PHA 2010-32-L SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"

24804010R

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorneys, and Respondent HUMANA PHARMACY, INC., doing business as RIGHTSOURCE (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was permitted by the Board of Pharmacy (hereinafter the "Board") as a pharmacy under Miscellaneous Permit Number PMP 473. The

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

permit was issued on or about June 13, 2006. The permit will forfeit or expire on or about December 31, 2013.

2. Respondent's mailing address for purposes of this action is 4302 W. Buckeye Road, Phoenix, Arizona 85043.

3. RICO received information that, on or about December 18, 2008, Respondent entered into a Consent Agreement with the Maine Board of Pharmacy in In Re: Humana Pharmacy, Inc./Complaint No. 2008-PHA-4787 ("Maine Agreement"). A true and correct copy of the Maine Agreement is attached hereto as Exhibit "1."

4. RICO alleges although Respondent disclosed the Maine Agreement on a Renewal Application dated December 7, 2009, Respondent failed to report the Maine Agreement to the Board within thirty days of its issuance.

5. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(15) (failure to report disciplinary decision within thirty days) and § 436B-19(17) (violating applicable licensing laws).

6. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein permitted as a pharmacy by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's permit.

6. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

7. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2010-32-L.

8. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

C. TERMS OF SETTLEMENT:

1. Administrative Fine. Respondent agrees to pay a fine in the amount of ONE THOUSAND AND NO/100 DOLLARS ($1,000.00). Payment shall be made by cashier's check or money order made payable to "DCCA - Compliance Resolution Fund" and mailed to the Regulated Industries Complaints Office, Attn: Denise P. Balanay, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this fully executed Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1 above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the permit to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible Further Sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of pharmacies in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5, C.6, C.7 and C.8 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain will raise as an objection in

any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: Louisville (CITY), Kentucky (STATE), 10-8-2012 (DATE).

HUMANA PHARMACY, INC.

By: _____

Its PRESIDENT HP&O

OCT 11 2012

DATED: Honolulu, Hawaii, _____.

DENISE P. BALANAY
Attorney for Department of Commerce
and Consumer Affairs

IN THE MATTER OF THE MISCELLANEOUS PERMITS OF HUMANA PHARMACY, INC., DOING BUSINESS AS RIGHTSOURCE; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; CASE NO. PHA 2010-32-L; EXHIBIT "1"

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

MARK E. BROWN
Chairperson

11-15-2012
DATE

PATRICK ADAMS
Vice Chairperson

TODD INAFUKU

GARRETT A. LAU

CAROLYN S.Y. MA

JILL OLIVEIRA GRAY

LYDIA KUMASAKA

PVL 07/15/11

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
HUMANA PHARMACY, INC.	)	CONSENT AGREEMENT
	)	
Complaint No. 2008-PHA-4787	)	

PARTIES

This document is a Consent Agreement regarding disciplinary action against Humana Pharmacy Inc.'s license to operate a mail order prescription pharmacy dispensing prescription drugs to patients residing in the State of Maine. The parties to this Consent Agreement are: Humana Pharmacy, Inc. ("Humana") with a principal place of business in Phoenix, Arizona, the State of Maine Board of Pharmacy ("the Board") and the Maine Office of the Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

FACTS

1. At all times pertinent to this matter, Humana was licensed by the Board to operate a mail order prescription pharmacy in Phoenix, Arizona dispensing prescription drugs to patients residing in Maine, license number MO40000472.
2. On or about July 10, 2008, the Board received a complaint against Humana pertaining to an alleged prescription order that was improperly sent to a consumer in Maine.
3. The Board docketed the complaint as Complaint No. 2008-PHA-4787.
4. The complaint alleges that on or about June 26, 2008, Humana sent a consumer residing in Maine prescription drugs that the consumer did not order.

EXHIBIT 7

5. The drug container was labeled by Humana with the name of the Maine resident and indicated that the prescribing practitioner was a physician from Florida.
6. Humana charged the cost of the drugs to the credit card of the Maine consumer and to Medicare.
7. On November 18, 2008, following a presentation of the complaint, the Board voted to offer Humana this Consent Agreement, in order to resolve Complaint No. 2008-PHA-4787. Absent acceptance of this Consent Agreement by signing and dating it and returning it to Kelly McLaughlin, Board Clerk, Board of Pharmacy, 35 State House Station, Augusta, Maine 04333-0035 by January 5, 2009, the Board will resolve this matter by holding an adjudicatory hearing.

COVENANTS

8. Humana admits that it was responsible for dispensing the erroneously filled prescription as described in paragraphs 4 through 6 above and admits that such conduct constitutes grounds for disciplining it pursuant to 10 M.R.S. § 8003(5-A)(A)(5), for violating a rule of the Board as follows:
    a. Chapter 30 § 15 by failing to establish and maintain effective controls to prevent prescription errors or misfills; and
    b. Chapter 30 § 16 by failing to address or attempt to resolve a possible prescription error which was apparent or should have been apparent.

9. As DISCIPLINE for the conduct admitted in paragraph 8 above, Humana agrees to

   a. Accept a WARNING; and

   b. Pay a CIVIL PENALTY in the amount of one hundred dollars ($100.00), which shall be made by check or money order payable to the "Treasurer, State of Maine" and delivered to Kelly McLaughlin, Board Clerk, Board of Pharmacy, 35 State House Station, Augusta, Maine 04333-0035, within thirty (30) days of the execution of this Consent Agreement.

10. Violation of any of the terms or conditions of this Consent Agreement by Humana shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

11. This Consent Agreement is not appealable and is effective until modified or rescinded by the parties hereto.

12. The Board and the Office of the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

13. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408.

14. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

15. Humana acknowledges by signature of an authorized representative hereto that it has read this Consent Agreement, that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executed this Consent Agreement of its own free will, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 12/18/08

For HUMANA PHARMACY, INC.

Print Name and Title

DATED: 12/31/08

LORI A. McKEOWN, R.Ph., President
Maine Board of Pharmacy

DATED: 12/29/2008

ANDREW L. BLACK
Assistant Attorney General

DEPT. OF COMMERCE
CONSUMER AFF.
2012 DEC 20 P 1:18
RECEIVED
2012 DEC 11 P 1:51

DENISE P. BALANAY 5526
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorney for Department of Commerce
and Consumer Affairs

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of HUMANA PHARMACY, INC., doing business as RIGHTSOURCE, Respondent.	)	PHA 2011-21-L SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"

248040108

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorneys, and Respondent HUMANA PHARMACY, INC., doing business as RIGHTSOURCE (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was permitted by the Board of Pharmacy (hereinafter the "Board") as a pharmacy under Miscellaneous Permit Number PMP 473.

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

The permit was issued on or about June 13, 2006. The permit will forfeit or expire on or about December 31, 2013.

2. Respondent's mailing address for purposes of this action is 4302 W. Buckeye Road, Phoenix, Arizona 85043.

3. RICO received information that, on or about May 9, 2011, Respondent entered into a Stipulation and Final Agency Order with the State Board of Pharmacy for the State of Colorado ("Stipulation"). A true and correct copy of the Stipulation is attached as Exhibit "1."

4. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s): Hawaii Revised Statutes ("HRS") § 436B-19(13) (disciplinary action by another state or federal agency for any reason provided by licensing laws) and § 436B-19(17) (violating applicable licensing laws).

5. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein permitted as a pharmacy by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's permit.

6. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

7. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2011-21-L.

8. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

C. TERMS OF SETTLEMENT:

1. Administrative Fine. Respondent agrees to pay a fine in the amount of FIVE HUNDRED AND NO/100 DOLLARS ($500.00). Payment shall be made by cashier's check or money order made payable to "DCCA - Compliance Resolution Fund" and mailed to the Regulated Industries Complaints Office, Attn: Denise P. Balanay, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this fully executed Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1 above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all

indicia of the permit to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible Further Sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of pharmacies in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

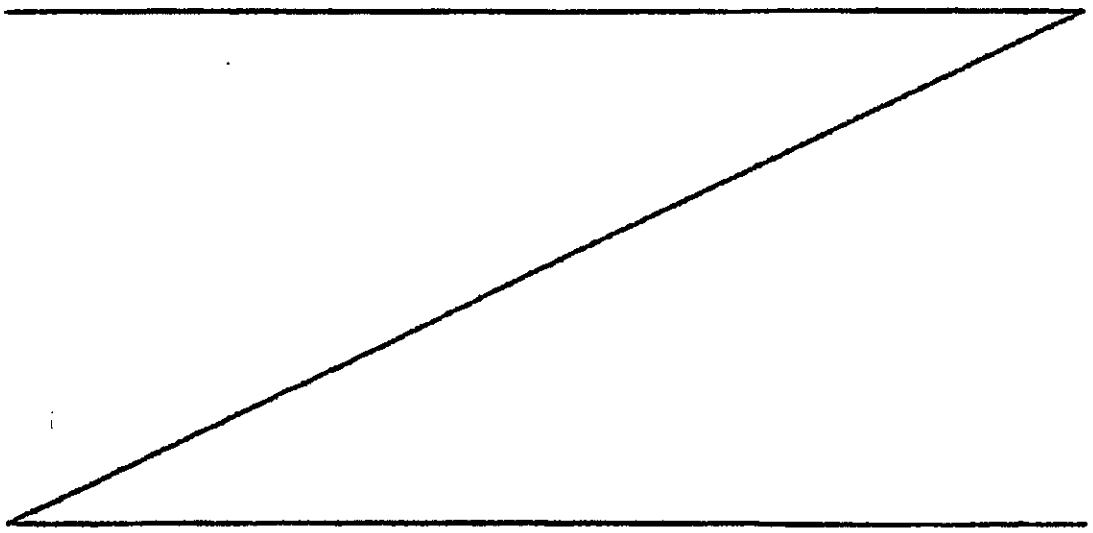
4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5, C.6, C.7 and C.8 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.



IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: Louisville (CITY), Kentucky (STATE), 10·8·2012 (DATE).

HUMANA PHARMACY, INC.

By: _____

Its _____

DATED: Honolulu, Hawaii, OCT 11 2012.

DENISE P. BALANAY
Attorney for Department of Commerce
and Consumer Affairs

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF HUMANA PHARMACY, INC., DOING BUSINESS AS RIGHTSOURCE; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; CASE NO. PHA 2011-21-L; EXHIBIT "1"

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

MARK E. BROWN
Chairperson

11/15/2012
DATE

PATRICK ADAMS
Vice Chairperson

TODD INAFUKU

GARRETT A. LAU

CAROLYN S. C. MA

JILL OLIVEIRA GRAY

LYDIA KUMASAKA

PVL 07/15/11

BEFORE THE STATE BOARD OF PHARMACY
STATE OF COLORADO

Case Nos. 2011-1151 and 2011-1153

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION OF HUMANA PHARMACY, INC., REGISTRATION NO. OSP 5672,

Respondent Pharmacy.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Humana Pharmacy, Inc. ("Respondent Pharmacy") to resolve all matters pertaining to Board Case Numbers 2011-1151 and 2011-1153, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Pharmacy, its registration as a non-resident prescription drug outlet, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S. (2010).

2. Respondent Pharmacy was originally registered as an non-resident prescription drug outlet in the State of Colorado on November 7, 2006, being issued registration number OSP 5672, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Pharmacy admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

4. Respondent Pharmacy's address of record with the Board and current location is 4302 West Buckeye Road, Phoenix, Arizona 85043.

5. On two separate occasions, Respondent Pharmacy failed to timely submit the required applications and fees to the Board detailing changes in pharmacist managers. In Board Case No. 2011-1151, a new pharmacist manager sent a letter to the Board on June 2, 2008 informing it that he had taken over as the new pharmacist manager, and asking if there was "anying further" required of him. However, the required application and fee were never submitted detailing him as the pharmacist manager during the 562-day time period that pharmacist served as manager between May 12, 2008 and February 1, 2010. In Board Case No. 2011-1153, 198 days elapsed during which time he served as [illegible] pharmacist manager between February 1, 2010 and August 19, 2010 when the application and fee were received detailing him as the new pharmacist manager.

RECEIVED
PROF & VOCATIONAL
2011 MAR 31 A
OFFICE OF COMPLAINT COORDINATOR AFFAIRS
STATE OF HAWAII

EXHIBIT "1"

6. Respondent Pharmacy's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drugs.

12-22-130. Nonresident prescription drug outlet - registration.

(4) (a) The board may deny, revoke, or suspend a nonresident prescription drug outlet registration for failure to comply with any provision of this section or with any reasonable rule promulgated by the board.

* * *

Pharmacy Board Rules

5.00.70 Change in Pharmacist Manager.

b. The registration of any in-state and non-resident prescription drug outlet shall become void if the pharmacist manager in whose name the registration was issued ceases to be engaged as the manager, and the owner shall close the outlet unless such owner has employed a pharmacist manager and, within fourteen days after termination of the former manager's employment, has made application to transfer the registration to the new pharmacist manager and has paid the transfer fee therefor.

* * *

7. The Board finds and concludes, and Respondent Pharmacy agrees, that based upon Respondent Pharmacy's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

RECEIVED
PROF. & VOCATIONAL
LICENSING DIVISION
'11 JUN -3 A 11:49
DEPT OF COMMERCE
& CONSUMER AFFAIRS
STATE OF HAWAII

TERMS OF DISCIPLINE

8. Fine with Surcharge. Pursuant to §12-22-125.2(5), C.R.S., Respondent Pharmacy shall pay a fine of Five Thousand Dollars and No Cents ($5,000.00). Respondent Pharmacy understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 10% of this fine. Respondent Pharmacy shall therefore pay a total amount of Five Thousand Five Hundred Dollars and No Cents ($5,500.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Pharmacy submits this signed Final Agency Order to the Board.

9. Compliance. Respondent Pharmacy shall submit all future applications, on the form prescribed by the Board, to the Board detailing changes in pharmacist manager and fees within fourteen (14) days of the previous pharmacist manager ceasing the position.

10. Other Requirements. Respondent Pharmacy acknowledges and agrees that, as a condition of this Final Agency Order and probation, it shall:

    a. promptly pay all its own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. Advisements and Waivers. Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, after having consulted with legal counsel. Respondent Pharmacy acknowledges its understanding that it has the following rights:

    a. to have formal notice of hearing and charges served upon it;

    b. to respond to said formal notice of charges;

    c. to have a formal disciplinary hearing pursuant to Sections 12-22-125 and 12-22-125.2(2)(a), C.R.S.; and

    d. to appeal this Final Agency Order.

    Respondent Pharmacy freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Pharmacy to the sanctions imposed herein.

12. Acknowledgements. Respondent Pharmacy has read this Final Agency Order, submits entirely and acknowledges, after having consulted with legal counsel, that Respondent Pharmacy

RECEIVED
PROF & VOCATIONAL
LICENSING DIVISION
2011 MAR -3 A 11:09
DEPT OF COMMERCE
& CONSUMER AFFAIRS
STATE OF HAWAII

understands its legal consequences and agrees that none of its terms or conditions is unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.

13. Violations. Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Pharmacy's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.

14. Integration and Severability. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

15. Public Record. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

Effective Date. This Final Agency Order shall become effective upon signature by a Board representative.

ACCEPTED AND AGREED BY

Respondent Pharmacy

William K. Lee / VP
Authorized Representative/Title

Dated: 5/9/11

Subscribed and sworn to before me in the County of Jefferson,
State of Kentucky, this 9 day of May, 2011 by
William Lee Irwin as authorized representative of Humana Pharmacy, Inc.

My commission expires: 2/8/15

Notary Public

CAROL KENSLEY
Notary Public
State at Large
Kentucky
My Commission Expires Feb 8, 2015

RECEIVED
2011 JUN 1 A 11:49
DEPT OF REGULATORY AGENCIES
& CONSUMER AFFAIRS
STATE OF HAWAII
PROFESSIONAL & VOCATIONAL LICENSING DIVISION

4

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 19th day of May, 2011.

State Board of Pharmacy

BY: _____
Wendy Anderson
Program Director

DOCUMENT APPROVED AS TO FORM

QUARLES & BRADY LLP

_____
CHRISTINE CASSETTA*

Attorneys for Respondent Pharmacy

One Renaissance Square
Phoenix, Arizona 85004-2391
Telephone: (602) 229-5258
FAX: (602) 420-5036
christine.cassetta@quarles.com
*Counsel of Record

JOHN W. SUTHERS
Attorney General

_____
JOANNA LEE KAYE, #20436*
Assistant Attorney General
Business and Licensing Section

Attorneys for State Board of Pharmacy

1525 Sherman Street, 5th Floor
Denver, Colorado 80203
Telephone: (303) 866-6170
FAX: (303) 866-5395
jo.kaye@state.co.us
*Counsel of Record

RECEIVED
PROF & VOCATIONAL
LICENSING DIVISION
2011 JUN -3 A 11:09
DEPT OF COMMERCE
& CONSUMER AFFAIRS
STATE OF HAWAII

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 19th day of May 2011, addressed as follows:

Christine Cassetta, Esq.
Quarles & Brady LLP
One Renaissance Square
Phoenix, Arizona 85004-2391

and via interagency mail to:

Jo Kaya
Assistant Attorney General

RECEIVED
PROF & VOCATIONAL
LICENSING DIVISION
2011 JUN -3 A 11:49
DEPT OF COMMERCE
& CONSUMER AFFAIRS
STATE OF HAWAII

BEFORE THE IOWA BOARD OF PHARMACY

Re: Nonresident Pharmacy License of **RIGHTSOURCE** License No. 3659 Respondent.	)	Case No. 2012-14 **SETTLEMENT AGREEMENT AND FINAL ORDER**

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2013), the Iowa Board of Pharmacy and RightSource, Respondent, enter into this Settlement Agreement and Final Order to settle the licensee disciplinary proceeding currently pending before the Board.

The allegations contained in a Statement of Charges against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. Respondent was issued Nonresident Pharmacy License No. 3659. That license is active and will expire on December 31, 2013.
2. A Statement of Charges was filed against Respondent on April 23, 2013. Subsequent to April 23, 2013, the parties entered into ongoing discussions regarding the allegations set forth in the Statement of Charges.
3. At all times relevant to the Statement of Charges, Respondent operated a nonresident pharmacy in Phoenix, Arizona.

RECEIVED
AUG 22 2013
IOWA BOARD OF PHARMACY

4. The Board has jurisdiction over the parties and the subject matter of these proceedings.

5. Respondent has chosen not to contest the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.

6. Respondent is hereby CITED for having disciplinary action taken against it by another state licensing board, and is hereby WARNED that future violations of the law governing the practice of pharmacy in Iowa could result in further disciplinary action.

7. Respondent agrees to pay a civil penalty in the amount of $1000. This civil penalty shall be made payable to the Treasurer of Iowa and mailed to the executive director of the Board within twenty (20) days of the Board's approval of this Settlement Agreement and Final Order. All civil penalty payments shall be deposited into the State of Iowa general fund.

8. This Settlement Agreement and Final Order is the resolution of a contested case. By entering into this Settlement Agreement and Final Order, Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges, and waives any objections to this Final Order.

9. The State's legal counsel may present this Settlement Agreement and Final Order to the Board.

10. This Settlement Agreement and Final Order is subject to approval by a majority of the full Board. If the Board fails to approve this settlement, it shall be

of no force or effect to either the Board or Respondent. If the Board approves this Settlement Agreement and Final Order, it shall be the full and final resolution of this matter.

11. The Board's approval of this Settlement Agreement and Final Order shall constitute a FINAL ORDER of the Board.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 15 day of August, 2013.

For Respondent

By this signature, Scott Greenwell acknowledges s/he is authorized to sign this Settlement Agreement and Final Order on behalf of RightSource.

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy on the 28th day of August 2013.

EDWARD L. MAIER, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Theresa O=Connell Weeg
Assistant Attorney General
Office of the Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

RECEIVED
JAN 29 2014
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
LICENSING SECTION

In the Matter of

RIGHT SOURCE
a/k/a Humana Pharmacy, Inc.
License Number: 53-01-008370

File Number: 53-13-128340
CONSENT ORDER AND STIPULATION

CONSENT ORDER

WHEREAS, an Administrative Complaint, hereafter Complaint, was issued on August 8, 2013, charging Right Source, a/k/a Humana Pharmacy, Inc., hereafter Respondent Pharmacy, with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq; and

WHEREAS, Respondent Pharmacy neither admits nor denies the facts alleged in the Complaint dated August 8, 2013, but agrees that the Disciplinary Subcommittee of the Michigan Board of Pharmacy, hereafter Disciplinary Subcommittee, shall treat the allegations as true for the purposes of this Consent Order, which findings shall have the same force and effect as if evidence and argument were presented in support of the allegations; and

WHEREAS, the Disciplinary Subcommittee has reviewed the Stipulation and, based upon the matters asserted therein, agrees that the public interest is best served by resolution of the outstanding Complaint; now therefore,

IT IS HEREBY FOUND that the facts alleged in the Complaint are true, for the purposes of this Consent Order, and constitute a violation of section 17768(2)(d) of the Public Health Code, supra.

Accordingly,

IT IS HEREBY ORDERED that for the cited violation of the Public Health Code, Respondent Pharmacy is FINED in the amount of $1,500.00 to be paid to the State of Michigan within 60 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs, Enforcement Division, Sanction Monitoring, P.O. Box 30189, Lansing, MI 48909.** The fine shall be paid by check or money order, made payable to the State of Michigan, and the check or money order shall clearly display file number **53-13-128340.**

IT IS FURTHER ORDERED that in the event Respondent Pharmacy violates any provision of this Order, the Disciplinary Subcommittee may proceed to take disciplinary action pursuant to 1996 AACS, R 338.1632 and section 16221(h) of the Public Health Code, supra.

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

Dated: 9/9/14

MICHIGAN BOARD OF PHARMACY

By: _____
Chairperson, Disciplinary Subcommittee

STIPULATION

1. Respondent Pharmacy neither admits nor denies the facts alleged in the Complaint dated August 8, 2013, but agrees that the Disciplinary Subcommittee shall treat the allegations as true for the purposes of this Consent Order, which findings shall have the same force and effect as if evidence and argument were presented in support thereof.

2. Respondent Pharmacy understands and intends that by signing this Stipulation Respondent Pharmacy is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq, to require the Department of Licensing and Regulatory Affairs, hereafter Department, to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent Pharmacy is waiving the right to appear with an attorney and such witnesses as Respondent Pharmacy may desire to present a defense to the charges.

3. Patricia Smeelink, R.Ph., a member of the Michigan Board of Pharmacy who supports this proposal, and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in the foregoing Consent Order.

4. The foregoing Consent Order is approved as to form and substance by Respondent Pharmacy and the Department and may be entered as the final order of the Disciplinary Subcommittee in this cause.

5. The foregoing proposal is conditioned upon acceptance by the Disciplinary Subcommittee, Respondent Pharmacy and the Department expressly reserving the right to further proceedings without prejudice should the Consent Order be rejected.

AGREED TO BY:

Carole H. Engle, Director
Bureau of Health Care Services
Department of Licensing and
Regulatory Affairs

Dated: 1-31-14

AGREED TO BY:

Michael Kuratko
Authorized Representative
for Respondent Pharmacy

Dated: 1/28/2014

This is the final page of a Consent Order and Stipulation in the matter of Right Source, a/k/a Humana Pharmacy Inc., File Number 53-12-128340, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of four pages, this page included.

AS

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

IMPOSITION OF CIVIL FINE
Case # 2014-000669

RightSource admits and agrees that the Alaska Board of Pharmacy (Board) has jurisdiction over the subject matter of their license in Alaska and over this Imposition of Civil Fine.

1. The Board alleges that RightSource during their Biennial license renewal periods from 2010-2012 and 2012-2014, failed to disclose information concerning prior licensing actions taken against one of their companies in 2008 which is in violation of 12 AAC 52.920 (a)(13) and 12 AAC 052.991.

2. RightSource admits this error was an oversight on their part and that they have taken steps to ensure this error does not occur again.

RightSource does not contest that the Board's allegations, which if proven could be grounds for possible denial of licensure or other disciplinary sanctions of their license pursuant to AS 08 80.030 (b)(5), AS 08.01.075, AS 08.80 261 and 12 AAC 52.920. In order to resolve this matter, RightSource is agreeing to this Imposition of a Civil Fine of one thousand dollars ($1000) in cash, certified check, or money order payable to the "State of Alaska" within ninety (90) days after this Imposition of Civil Fine is accepted by the Board

RightSource has the right to consult with an attorney and the right to have an administrative hearing on the facts in this case. RightSource understands and agrees that by voluntarily signing this Imposition of Civil Fine, they are waiving their rights to counsel and to a hearing on this matter.

On Behalf of RightSource — Date: 7/25/2014

ORDER

The Alaska Board of Pharmacy hereby adopts the Imposition of Civil Fine in this matter. The Board has determined that this violation of professional licensing statutes and regulations can be resolved with a civil fine.

This Imposition of Civil Fine takes effect immediately upon signature of this Order in accordance with the approval of the Board.

DATED this 7th day of AUGUST, 2014, at ANCHORAGE, Alaska.

BOARD OF PHARMACY

By: _____
Dirk White-Chairperson

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

Amber Enterprises, Inc. d/b/a Amber Specialty Pharmacy

Officers and Directors

Name	Title
Bethanie Lynn Stein	President
Sean Michael Lysinger	Vice President, Chief Financial Officer, Pharmacy
Robert Martin Marcoux, Jr.	Director, Vice President and Treasurer
Daniel Kevin Feld	Director & Associate Vice President, Tax
Valerie M. Talkers	Director, Vice President, Associate General Counsel and Corporate Secretary

The Pharmacy is wholly owned by
Amber Enterprises, Inc. d/b/a Amber Specialty Pharmacy
FEIN: 47-0723983
10004 S 152nd St. Ste. A
Omaha, NE 68138

Amber Enterprises, Inc. d/b/a Amber Specialty Pharmacy is wholly owned by
CenterWell Pharmacy, Inc.
FEIN: 61-1316926
101 East Main Street
Louisville, KY 40202

STATE OF NEBRASKA

United States of America, } ss.
State of Nebraska }

Secretary of State
State Capitol
Lincoln, Nebraska

I, Robert B. Evnen, Secretary of State of the State of Nebraska, do hereby certify that

AMBER ENTERPRISES, INC.

incorporated on February 8, 1989 and is duly incorporated under the law of Nebraska;

that no occupation taxes due from and assessable against the Corporation are unpaid and have become delinquent;

that no annual or biennial report required to be forwarded by the Corporation to the Secretary of State has become delinquent;

that Articles of Dissolution have not been filed.

This certificate is not to be construed as an endorsement, recommendation, or notice of approval of the entity's financial condition or business activities and practices.

In Testimony Whereof,

I have hereunto set my hand and affixed the Great Seal of the State of Nebraska on this date of

May 11, 2026

Secretary of State

Verification ID 03ab44b has been assigned to this document. Go to ne.gov/go/validate to validate authenticity for up to 12 months.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Amber Enterprises, Inc. d/b/a Amber Specialty Pharmacy

Pharmacy/Wholesaler License # (if applicable): PH02178

Physical Address: 10004 S. 152nd St., Suite A

City: Omaha State: NE Zip: 68138

Mailing Address (if different from physical address): [Same as physical address]

City: State: Zip:

Telephone: 402-896-5000 Website: www.amberpharmacy.com

Licensing Company Email: licensure@amberpharmacy.com

Section 2: Personal Information

First: Pamela Middle: Anne Last: Helser

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Omaha State: NE Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: UNMC			From - To (MM/YY – MM/YY): 9/02 - 5/06
Address:	City: Omaha	State: NE	Zip:
Diploma/Degree obtained, if any: Pharm D			
School Name: UNL			From - To (MM/YY – MM/YY): 9/00 - 5/02
Address:	City: Lincoln	State: NE	Zip:
Diploma/Degree obtained, if any: Pre Pharmacy			
School Name: Papillion LaVista high			From - To (MM/YY – MM/YY): 8/96 - 5/00
Address:	City:	State: NE	Zip:
Diploma/Degree obtained, if any: Diploma			
School Name:			From - To (MM/YY – MM/YY):
Address:	City:	State:	Zip:
Diploma/Degree obtained, if any:			
School Name:			From - To (MM/YY – MM/YY:
Address:	City:	State:	Zip:
Diploma/Degree obtained, if any:			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): 05/17-current	[redacted]	City: Gretna	State: NE	[redacted]
From - To (MM/YY – MM/YY): 10/05-04/17		City: Omaha	State: NE	
From - To (MM/YY – MM/YY):	Address:	City:	State:	Zip:
From - To (MM/YY – MM/YY):	Address:	City:	State:	Zip:
From - To (MM/YY – MM/YY):	Address:	City:	State:	Zip:
From - To (MM/YY – MM/YY):	Address:	City:	State:	Zip:
From - To (MM/YY – MM/YY):	Address:	City:	State:	Zip:
From - To (MM/YY – MM/YY):	Address:	City:	State:	Zip:
From - To (MM/YY – MM/YY):	Address:	City:	State:	Zip:
From - To (MM/YY – MM/YY):	Address:	City:	State:	Zip:

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Amber Specialty Pharmacy			From - To (MM/YY – MM/YY): 04/08-current	
Business Address: 10004 S 152nd St Ste. A		City: Omaha	State: NE	Zip: 68138
Phone	Title: pharmacist/ PIC		Number of Employed Hours: 40hr/wk x 18 yrs	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Pamela Helser, **certify that as the designated representative for**

Amber Enterprises, Inc. d/b/a Amber Specialty Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. PH I am at least 21 years of age;
3. PH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. PH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. PH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. PH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. PH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Pamela Helser

Print Name (First, Last)

Pamela Helser

Original Signature (electronic, copies or stamps not accepted)

7-13-2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Pamela Helser

Print Name (First, Last)

Pamela Helser

Original Signature (electronic, copies or stamps not accepted)

7-13-2026

Date

Please have this section completed in the presence of a Notary Public.

State of Nebraska, ss. County of Sarpy

I, Pamela Helser, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Pamela Helser

Original Signature

7-13-26

Date

Subscribed and Sworn to before me this 13 day of July 2026

Cathy Cattlett

Notary Public Signature

GENERAL NOTARY-State of Nebraska
CATHY CATTLETT
My Comm. Exp. July 15, 2028

(Seal)

NEBRASKA
Good Life. Great Mission.
DEPT. OF HEALTH AND HUMAN SERVICES

Jim Pillen, Governor

Public Health Licensure Unit
Certification of Licensure

This certificate serves as primary source verification of licensure in the State of Nebraska as of the close of the business day before 7/ 6/2026.

Name:	Amber Enterprises, Inc dba Amber Specialty Pharmacy
Owner:	Amber Enterprises, Inc dba Amber Specialty Pharmacy
Address:	10004 S 152nd ST, STE A, Omaha, NE
Type:	Provisional Pharmacy License
Number:	901
Status:	Active
Issued:	07/01/2026
Expiration:	07/01/2027

Disciplinary/Non-Disciplinary Information:

No disciplinary/non-disciplinary actions taken against this license.

If you have questions about this information, please contact the Licensure Unit at (402) 471-2115 or DHHS.LicensureUnit@nebraska.gov.

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Business e-Profile ID:	787800		**Inspection Information**
Legal Business Name:	Amber Enterprises, Inc.	**Conference Call Date:**	10/9/2025
Doing Business As (DBA):	Amber Specialty Pharmacy	**Start Time: 24-hour format (13:00)**	10:15
Address:	10004 S 152nd St, Ste A	**End Time: 24-hour format (13:00)**	11:15
City:	Omaha	**Onsite Inspection Date(s):**	10/14/2025
State:	Nebraska	**Start Time(s): 24-hour format (13:00)**	8:30
Zip Code:	68138	**End Time(s): 24-hour format (13:00)**	13:15
Telephone number:	402/896-5000	**Inspector Name(s):**	Fred Massoomi, RPh
Toll free number:	888/370-1724	**Inspection performed by (NABP, State, etc):**	NABP
Fax number:	402/896-3774	**Observer Name/Affiliation (if applicable):**	N/A
Website:	www.amberpharmacy.com	**Observer Name/Affiliation (if applicable):**	N/A

Focused Information

The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.

Nonsterile - 3.0, 3.1, 3.2, 14.0, 15.0 - 15.7, 18.0, 18.3, 21.0, 27.0, 27.3, 28.0, 28.5, 28.7, 29.0, 29.3, 36.0, 42.0, 42.1, 44.0, 44.4 - 44.7, 58.0, 58.18, 61.0 - 61.4

Additional information on NABP's Inspection website.

NABP Disclaimer: NABP can only verify the authenticity of an Inspection Report if it is transmitted directly from NABP to an intended recipient. NABP cannot verify the authenticity of an Inspection Report transmitted from any other party.

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			X
Monday	7:00	19:00	
Tuesday	7:00	19:00	
Wednesday	7:00	19:00	
Thursday	7:00	19:00	
Friday	7:00	19:00	
Saturday	7:00	17:00	

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Pamela Helser	phelser@amberpharmacy.com	188703
Nonsterile Designated person(s)	Lori Wells	lwells@amberpharmacy.com	145715
Sterile Designated person(s)	N/A	N/A	N/A
Hazardous Designated person(s)	N/A	N/A	N/A

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Margaret Sargent	Pharmacy Technician	Y
2	Sydney Ash	Pharmacy Technician	Y
3	Reeghan Kaminski	Pharmacy Technician	Y
4	Shannon Thomas	Pharmacy Technician	Y
5	Elizabeth Pilachowski	Pharmacy Technician	Y
6	Jennifer Howder	Pharmacist	Y
7	Amy Adams	Pharmacist	Y
8	Jill Allard	Pharmacist	Y
9	Amy Barry	Pharmacist	Y
10	Pamela Helser	Pharmacist	Y

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
Nebraska Department of Health and Human Services	Amber Enterprises, Inc dba Amber Specialty Pharmacy	Pharmacy	3009 & 7/1/2026
Drug Enforcement Administration	Amber Specialty Pharmacy	Pharmacy	FA4576712 & 6/30/2028

Inspector Notes: List states in which Non-Resident licenses are held: AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY. MA licensure expiration date: 12/31/2025. The pharmacy has a pharmacy license for the US Virgin Islands.The pharmacy ships to Puerto Rico. The pharmacy does not order or stock ReliOn insulin. The pharmacy does not compound semaglutide, tirzepatide, survodutide, cagrilintide, mazdutide or retatrutide preparations. The pharmacy does not purchase products from platforms that are a marketplace for pharmacies to buy, sell and bid on overstock and short dated prescription drugs. The pharmacy does not compound or repackage biological products. The pharmacy does not perform compounding with APIs. The pharmacy performs 'White Bagging'; Photo01_PI. The pharmacy has a segregated space within the main pharmacy with a segregated line defining the compounding space. The estimated compounding space is 24 sq ft.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Photo01_PI	Picture of a label for a white bagging product.

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail		Central Fill/Processing/Shared Services	X
Open to the Public	X (primarily closed door)	Nuclear Pharmacy	
Closed Door		Specialty Pharmacy	
Drive-through window		White bagging/ clear bagging	X
Mail- in state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	Outsourcing Facility	
Mail- out of state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	FDA Registered Drug Establishment (eg Manufacturer, repackager, relabeler)	
Local Delivery (if out of state describe in note)	X	Wholesale Distributor	
Veterinary Pharmacy (occasionally dispenses prescriptions for animals)		Provide prescription drugs for "Office Use" (eg distributes)	
Institutional (hospital or correctional facility)		Handles Medical Marijuana	
Long-Term Care (nursing home, residential care)		Nonsterile Compounding	X
Investigational Drugs, Clinical Trials/Research		Nonsterile Hazardous Drug Compounding	
Telepharmacy		Sterile Compounding	
Internet Pharmacy		Sterile Hazardous Drug Compounding	

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)		CSPs with controlled substance(s)	
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements (includes total parenteral nutrition)	
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement; and state if patient specific or distributed	
Patient specific (compounded preparation labeled for an individually identified patient):		**Patient specific** (compounded preparation labeled for an individually identified patient):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients	X	CSPs for human patients	
Distributed (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):		**Distributed** (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients	X	CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Types of CNSPs:		Categories of CSPs:	
Aqueous	X	Category 1 CSPs	
Nonaqueous		Category 2 CSPs	
Specific types:		Category 3 CSPs	
Solid oral preparations		Types of CSPs:	
Liquid oral preparations	X	Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations		Proprietary bag and vial systems	
Topical preparations:		Blood-derived or other biological material (eg autologous serum)	
Nasal and sinus preparations:		Sterile injections/ sterile infusions	
Other (please list):		Ophthalmic dosage forms	
		Baths and soaks for live organs and tissues	
		Implants/ Pellets	
		Other (please list):	

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Facility Size in Square Feet *(can be approximated)* and Number of PECs		Personnel	
Total Pharmacy size:	4,842	Total Pharmacists:	13
Nonsterile Compounding Room size:	24	Number of Compounding Pharmacists:	4
Nonsterile Compounding powder hoods number:	0	Total Student Interns:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	N/A	Total Technicians:	8
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	N/A	Number of Compounding Technicians:	2
Sterile Compounding Ante Room size:	N/A	Of technicians, how many are nationally certified?	6
Sterile Compounding Clean/Buffer Room size:	N/A	Of technicians, how many are techs-in-training?	2
Sterile Compounding Number LAFW hoods/areas:	N/A	Total Other Unlicensed Personnel:	14
Sterile Compounding Number BSC hoods:	N/A	Ratio #Technician(s) : #Pharmacist(s) present at time of inspection:	4:1
Sterile Compounding Number CAI/CACI hoods:	N/A	If multiple compounding suites are present under this licensed location (eg outsourcing facilities or hospital health systems), describe in notes other spaces where compounding occurs (eg location name, approximate size of space, and number and type of PECs:	N/A
Negative Pressure Sterile HD Room size:	N/A		
Sterile HD Compounding Number of BSC hoods:	N/A		
Sterile HD Compounding Number of CACI hoods:	N/A		

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	N/A
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	N/A

	Volume Dispensed		**Volume Distributed**
Total Prescriptions Dispensed/day:	1,300	Total Orders Distributed/day:	0
% Veterinary Prescriptions	0%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	1%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	1%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	0%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	35%	% Hazardous Drugs (HD) Orders	0%

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):

Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)	498	0	September 2025
Alaska (AK)	22	0	September 2025
Arizona (AZ)	280	0	September 2025
Arkansas (AR)	77	0	September 2025
California (CA)	383	0	September 2025
Colorado (CO)	427	0	September 2025
Connecticut (CT)	513	0	September 2025
Delaware (DE)	29	0	September 2025
District of Columbia (DC)	22	0	September 2025
Florida (FL)	775	0	September 2025
Georgia (GA)	319	0	September 2025
Hawaii (HI)	42	0	September 2025
Idaho (ID)	165	0	September 2025
Illinois (IL)	960	0	September 2025
Indiana (IN)	554	0	September 2025
Iowa (IA)	858	0	September 2025
Kansas (KS)	266	0	September 2025
Kentucky (KY)	599	0	September 2025
Louisiana (LA)	573	0	September 2025
Maine (ME)	27	0	September 2025
Maryland (MD)	229	0	September 2025
Massachusetts (MA)	292	0	September 2025
Michigan (MI)	812	0	September 2025
Minnesota (MN)	311	0	September 2025
Mississippi (MS)	148	0	September 2025
Missouri (MO)	629	0	September 2025
Montana (MT)	113	0	September 2025

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):

Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)	427	0	September 2025
Nevada (NV)	468	0	September 2025
New Hampshire (NH)	40	0	September 2025
New Jersey (NJ)	464	0	September 2025
New Mexico (NM)	93	0	September 2025
New York (NY)	326	0	September 2025
North Carolina (NC)	550	0	September 2025
North Dakota (ND)	36	0	September 2025
Ohio (OH)	1,074	0	September 2025
Oklahoma (OK)	209	0	September 2025
Oregon (OR)	203	0	September 2025
Pennsylvania (PA)	299	0	September 2025
Rhode Island (RI)	39	0	September 2025
South Carolina (SC)	215	0	September 2025
South Dakota (SD)	157	0	September 2025
Tennessee (TN)	503	0	September 2025
Texas (TX)	489	0	September 2025
Utah (UT)	342	0	September 2025
Vermont (VT)	10	0	September 2025
Virginia (VA)	460	0	September 2025
Washington (WA)	479	0	September 2025
West Virginia (WV)	75	0	September 2025
Wisconsin (WI)	319	0	September 2025
Wyoming (WY)	47	0	September 2025
Other: Puerto Rico; US Virgin Islands	21; 0	0; 0	September 2025; September 2025

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
	General Pharmacy		
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite*	Yes	The PIC is scheduled 40 hours a week on site.
3.00	Are there any other businesses located at this address? *If yes, note type of business and name*	Yes	Hy-Vee Pharmacy Solutions is located in Suite C of the building, and Amber Specialty Pharmacy is located in Suite A of the building. The pharmacies sit adjacent to each other and are separated by a wall with windows and a locked door that leads out to a shared receiving / dock area. Both pharmacies are licensed separately. Amber Specialty Pharmacy is owned by Amber Acquisition, which is owned by Hy-Vee, Inc. Hy-Vee Pharmacy Solutions is owned by HYVACS, LLC which is owned by Hy-Vee, Inc.
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs*	Yes	www.amberpharmacy.com
4.01	Does the pharmacy hold .pharmacy verification?	Yes	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	Yes	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe*	Yes	There is patient app 'amberspecialtypharmacy' where patients can order and refill prescriptions.
8.00	Are photographs allowed during the inspection (**no PHI**)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		Reeghan Kaminski, Certified Pharmacy Technician; Sydney Ash, Certified Pharmacy Technician; Kelli Wyant, Vice President of Operations

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
	Types of Practice Additional Questions **If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	Yes	Within Nebraska 10% go directly to the provider. 5% of total prescriptions sent out of state are sent to provider offices or infusion clinics for administration to patients.
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
	General Operations and Licensure **If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	Yes	Nebraska pharmacy licensure, DEA registration and accreditation certificates are posted in the main lobby. Non-resident state pharmacy licensures are located in an easily retrievable binder. This is a primarily a closed door pharmacy.
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	Last NE BOP inspection conducted an on-site on 6/9/2022. The NE BOP inspection cycle is 5 years.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	Yes	Deficiencies note: 1. Faxed CS prescriptions void of provider DEA numbers and 2. CS RX refill request sent using prepopulated request forms. These deficiencies were corrected.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item*	No	
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	URAC Specialty Pharmacy Accreditation, Effective: 3/1/2025, Expiration: 3/1/2028; URAC Rare Disease Accreditation, Effective: 3/1/2025 Expiration: 3/1/2028; ACHC Specialty Pharmacy Accreditation, Effective: 10/15/2024, Expiration: 10/14/2027; ACHC DMEPOS Accreditation, Effective: 10/15/2024, Expiration: 10/14/2027; ACHC Oncology, Effective: 10/15/2024, Expiration: 10/14/2027; NABP Digital Pharmacy, Effective: 3/5/2024, Expiration 3/4/2027.
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	Records are kept on site for 10 years.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	Written and verbal prescriptions are kept on site for 10 years.
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy)*	Yes	Electronic prescriptions are kept on site indefinitely in the clinical system CareTend.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy)*	Yes	Dispensing records are kept on site indefinitely in the clinical system CareTend.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy)*	Yes	CareTend clinical system is used and pharmacy records are kept indefinitely and prevents the deletion of prescriptions once dispensed.
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	No records are stored off site.
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	SOP A-1001 Compliance with Federal, State, & Local Laws Rules & Regulations has the statement.

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	Cathy Cattlet, Licensing Manager oversees licensing and registrations for the pharmacy. LicenseTrak is used to track and monitor all professional and registration licensures. On a quarterly basis, managers conduct routine reviews of the NE BOP for licensure and registration status.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	The Licensing Manager uses LicenseTrak to monitor licensures and registrations. Monday.com is used to verify pharmacy technicians are up to date for registrations. The review is performed by the PIC once a quarter.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	4:1 on inspection.
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	The building has a security guard on site M-F 8 am to 5 pm. The building security system is managed by A+ Communications and Security Systems. The security system has a keypad entry with a unique code to personnel, personnel badge entry into the pharmacy space, motion sensors and camera recording. Non-pharmacy personnel are not allowed to enter the licensed pharmacy space.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	N/A	The pharmacy does not order CII schedule drugs.

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	SOP A-4006 Emergency Preparedness & Disaster Recover Plan outlines the process for securing the medications. Medications would be moved to an alternative, local Hy- Vee pharmacy location following NE BOP of approval.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	Inmar
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	Medical Waste Vendors: MedShred and Amergy. Pick up is scheduled every 3 months.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	Yes	Although listed as a 'closed door pharmacy' the pharmacy does have a small room assigned for patient counseling.

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection*	Yes	Continuous temperature monitoring system: SmartSense. Room temperature at the time of inspection for the drug storage area: 69.4°F.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Yes	SmartSense takes a reading every 15 minutes and alerts the PIC via text and email at the moment the temperature is out of range.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	SmartSense takes a reading every 15 minutes and alerts the PIC via text and email at the moment the temperature is out of range. Temperature probes are set at 68°F to 77°F. Records are kept indefinitely within the SmartSense system.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection*	Yes	Temperature Monitoring System: SmartSense. Refrigerator temperature range setting is 36°F to 46°F: Medication refrigerator #1: 43.1°F; Medication refrigerator #2: 39.8°F; Medication refrigerator #3: 40.4°F; Medication refrigerator #4: 40.4°F
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	No	The freezer is not used for medication storage. Records are kept indefinitely within the SmartSense system.

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	The pharmacy has a back up generator that runs on natural gas. If a refrigerator or freezer goes out of operation, products will be moved to another unit. If there is not enough space for the products, they will be relocated to a local Hy-Vee Pharmacy location pending NE BOP approval.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	The pharmacy has a contract with the local HVAC company Hussman HVAC in Omaha, NE, for maintenance and emergencies.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	No	
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	N/A	

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
	Product Receipt and Inventory **If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe*	Yes	The corporate office has a Sourcing Team that validates vendors that have the proper licensing for Nebraska. The individual pharmacy is not allowed to purchase medications outside of the approved vender list.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	Yes	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase*	Yes	The pharmacy purchases drugs from affiliate pharmacies located within the Hy-Vee, Inc. network.
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources*	Yes	Approved wholesalers: Accord; Alkermes; Amerisource Bergen Corp. (now Cencora); ANDA; ASD; Astellas; BioRidge; Cardinal Health; Cardinal Specialty; Celgene; ChemoCentryx; FFF Enterprises; Greenwich Biosciences; Hercules; Hy-Vee Warehouse; Incyte; Indivior; Kadmon; Mayne Pharma; McKesson; Neurocrine; PTC Therapeutics; Sanofi; Zealand
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	Yes	The corporate office has a Sourcing Team that validates vendors.
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	No	

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	Yes	The corporate Sourcing Team validates and enters all transactions documents into InfiniTRAK.
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	Yes	The corporate Sourcing Team validates and enters all transactions documents into InfiniTRAK.
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	Suspect and illegitimate products would be quarantined. The PIC would notify the corporate Sourcing Team who would contact manufacture and the wholesaler to validation the product.
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	None to date.
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	Yes	Inspector viewed transaction documents for the following drugs with InfniTRAK: Tasigna® and Apretude®. Data is kept in the system indefinitely.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	The product will be quarantined and the corporate Sourcing Team would be notified to investigate. SOP A-6005 Drug Supply Chain Security defines the process.
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	Yes	Pharmacy has DEA 222 forms on site, but has not ordered any CII's. Forms are stored in a locked cabinet with access by the PIC. Kelli Wyant, Senior Vice President of Operations is the registrant and Power of Attorney for both Pamela Helser (PIC) and Amy Adams (pharmacist).

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	N/A	
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	N/A	
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Yes	Schedule III-V invoices are checked in by a pharmacy technician and approved by a pharmacist. All invoices reviewed have duel signatures and dates.
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity)*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	The pharmacy conducts a monthly on-hand inventory and compares the inventory to what has been received and dispensed.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made*	Yes	Diversion events would be reported to corporate human resources and to the NE BOP. Resignations are reported to corporate human resources.

Copyright © July 2024 National Association of Boards of Pharmacy® (NASP®). All rights reserved. NABP developed this inspection form for sole use by NABP boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	N/A	
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	N/A	
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	Current Controlled Substances inventory taken on 5/2/2025. Zero inventory noted for CIIs dated 10/9/2025.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	Change of PIC inventory took place on 9/27/2024.
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	The pharmacy has a separate cart segregated from viable stock that is clearly labeled 'Expired Medications'.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	
60.02	How often is active-stock examined for drugs past the expiration date?		The cycle counts are every 4 weeks when expiration dates are reviewed. Drugs are pulled 60 days prior to the expiration date.
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	Yes	
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	Yes	

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
	Prescription Processing **If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Patient information is entered in CareTend by the intake team. Patient information is updated at least annually or with each communication touch point with the patient or provider.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	N/A	
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process*	Yes	Intake staff look for missing information in the profile and a mismatch of patient residence to provider location. If identified, a pharmacist would be alerted and the pharmacist would contact the provider to clarify information.
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	Intake staff look for mismatch of patient residence to provider location. If identified, a pharmacist would be alerted and the pharmacist would contact the provider to clarify information.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both*	Yes	The pharmacy has electronic capability for electronic controlled substance and non-controlled substances prescriptions.

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	Accuracy of prescription information is managed through the verification queue which is conducted by a pharmacist at the PV1 step.
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	DUR information is reviewed twice by a pharmacist at PV1 and PV2.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe*	Yes	Tzield® requires a laboratory test prior to dispensing.
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	Lexicomp and NASP membership resources.
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe*	Yes	Data is submitted each evening to the required PMP states.

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	SOP A-5001 Controlled Substances outlines the steps.
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	CareTend documents all DUR overrides. Only pharmacist can override DURs.
67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	Yes	CareTend uses Medispan as the drug database.
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	All specific DUR criteria outside of the standard DUR template are documented in Care Tend.
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	N/A	
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	The PV2 step has a pharmacist review the prescription with the order with product or preparation.
69.00	Are filled prescriptions appropriately labeled? *Describe*	Yes	Labels are generated out of CareTend at the time of dispensing at PV2.

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
70.00	**Confidentiality**: Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used*	Yes	CareTend has access limited by job function and unique staff passwords.
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
75.01	Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	The offer to counsel is provided by a pharmacist.
76.00	Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	No	

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer"*	Yes	The offer to counsel is provided proactively by a pharmacist. This can happen but would be a rare infrequent event.
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	No	
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer"*	Yes	The offer to counsel is provided by a pharmacist.
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how*	Yes	The offer to counsel is given by intake personnel. Counseling is provided at the time the order is placed by a pharmacist.
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how*	Yes	Counseling is provided at the time the order is placed by a pharmacist.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how*	Yes	CareTend prints PPIs with each prescription order.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how*	Yes	CareTend prints MedGuides with each prescription order when indicated.
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin or Tikosyn)*	Yes	REMS programs: Sublocade®; Bosentan; Siliq Rem; Vigabatrin; Brixadi®; Spravato®; Revlimid®; Pomalyst®; Thalomid®

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how*	Yes	Both counseling and refusal of counseling are documented in CareTend.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation)*	Yes	The pharmacy as a 24 hour on call service that contacts the pharmacist who is on call to contract a patient or provider.
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	
	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program*	Yes	The program is overseen by Jennifer Tinnemeier, Corporate Quality Assurance.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both*	Yes	SOPs are available in both hard copy and electronic. SOP A-1002 Policy and Procedure Development, Review, Approval and Maintenance Process outlines the process.

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	SOP A-7000 Quality and Process Improvement Policy outlines the quality program. SOP A-7004 Quality Management Program outlines the steps for addressing: -Client, Customer and Provider Satisfaction Surveys -Incident Reporting -Complaint Process -Quality Management Program -Telephone Performance Monitoring
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	QREs are documented within the proprietary electronic system Cascade.
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP boards of pharmacy, government agencies that regulate drug distributors and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc)*	Yes	The Quality Program Team analyze the events for any contributing factors at a scheduled quarterly meeting.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	Quality meetings are held quarterly and meeting notes are provided to staff from each meeting.
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Notes
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	The Quality Program Team reports QRE information to Adherence for Patient Medication Safety (APMS) database.
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	The Quality Program Team reports QRE information to MedWatch through the Cascade system.
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	Yes	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	Site audits are performed quarterly as part of the CQI program. Last internal audit was 9/10/2025.
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	Yes	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	Patient complaints are tracked electronically through Cascade.

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)		**Please note NABP did not review each SOP for alignment on USP <795>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**	
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? ***If no, document "missing" in Inspector Notes*** ***If yes, document the name, number, and version of each SOP in the Inspector Notes.***	Yes		11
1.1	**Buildings and Facilities:** The pharmacy has an SOP for the compounding facility. ***Inspector note: Per USP <795>, there is a written SOP for "the method of designation" for the area designated specifically for nonsterile compounding and processes for maintaining, cleaning, and sanitizing the compounding area and equipment.***		SOP A-6020 Non-Sterile Compounding Written Control Procedures and Guidelines; pages 334-335	4.1, 5, 11
1.2	**Personnel Training and Evaluation:** The pharmacy has an SOP describing the training program, the frequency of training, and the process for evaluating the competency of personnel. ***Inspector note: Per USP <795>, "Facility SOPs must describe procedures for monitoring and observing of compounding activities and personnel."***		SOP A-6020 Non-Sterile Compounding Written Control Procedures and Guidelines; pages 343-337	2, 11
1.3	**Personal Hygiene and Garbing:** The pharmacy has an SOP regarding personal hygiene, glove, and garbing requirements consistent with compounding activities. ***Inspector note: Per USP <795>, "Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs."***		SOP A-6020 Non-Sterile Compounding Written Control Procedures and Guidelines; page 331	3.3, 11

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
1.4	**Components:** The pharmacy has an SOP describing selection, handling, storage, and inventory control of all components used in compounding. ***Inspector note: Per USP <795>, "The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP."***		SOP A-6020 Non-Sterile Compounding Written Control Procedures and Guidelines; pages 330; SOP A-6005 Drug Supply Chain Security; SOP A-6008 Inventory Storage and Security	6.2, 11
1.5	**Temperature Monitoring:** The pharmacy has an SOP regarding temperature monitoring and handling of excursions. ***Inspector note: Per USP <795>, "The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s)."***		SOP A-6008 Inventory Storage and Security; pages 263-264	4.2, 11
1.6	**Equipment**: The pharmacy has an SOP for assessment of need for closed system processing devices (based on the types of CNSPs prepared). ***Inspector note: Per USP <795>, "Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of closed-system processing devices include containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented."***		SOP A-6020 Non-Sterile Compounding Written Control Procedures and Guidelines; page 335	6.1, 11

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
1.7	**Safety Data Sheet (SDS)/Spill Management:** The pharmacy has an SOP describing spill management and disposal. ***Inspector note: Per USP <795>, "The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs."***		SOP A-6020 Non-Sterile Compounding Written Control Procedures and Guidelines; pages 343-349	6.2.5, 11
1.8	**Master Formulation Records (MFR):** The pharmacy has an SOP on the process for MFR creation and content. ***Inspector note: Per USP <795>, "Any changes or alterations to a Master Formulation Record are approved and documented in accordance with the facility's written SOP."***		SOP A-6020 Non-Sterile Compounding Written Control Procedures and Guidelines; pages 335-338	7.1, 11
1.9	**Labeling:** The pharmacy has an SOP on the processes for labeling, label verification (confirming against the prescription or medication order, the MFR, and the compounding record (CR)) in order to prevent errors and CNSP mix-ups and required displayed information. ***Inspector note: Per USP <795>, "Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups."***		SOP A-6020 Non-Sterile Compounding Written Control Procedures and Guidelines; pages 336-341	9, 11
1.10	**Quality Assurance (QA)/Quality Control (QC) Program:** The pharmacy has an SOP regarding its QA and QC program, including roles of the designated person(s), trainers, compounding personnel; adherence to procedures; and prevention and detection of errors and quality issues. ***Inspector note: Per USP <795>, "QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter, and laws and regulations of the applicable regulatory jurisdiction."***		SOP A-6020 Non-Sterile Compounding Written Control Procedures and Guidelines; pages 349-356	11, 12 USP <1163>

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
1.11	**QA/QC Program Complaint Handling and Adverse Event Reporting:** The pharmacy has an SOP for evaluation of complaints and adverse events, including investigations and corrective actions. ***Inspector note: Per USP <795>, the pharmacy, "must develop and implement SOPs for complaint handling." SOPs are to include any state or federal requirements for reporting to government agencies (example adverse event reporting). Further, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease compounding until problems have been identified and corrected."***		SOP A-6020 Non-Sterile Compounding Written Control Procedures and Guidelines; page 343; SOP A-4002 Call Escalation and Complaint Tracking Process; pages 145-148	1.1.3, 11, 12.1, 12.2, 12.3
1.12	**Packaging:** The pharmacy has an SOP describing packaging CNSPs. ***Inspector note: Per USP <795>, "SOPs must describe packaging of CNSPs."***		SOP A-6020 Non-Sterile Compounding Written Control Procedures and Guidelines; page 340	11, 13.1
1.13	**Transporting:** The pharmacy has an SOP describing transporting CNSPs. ***Inspector note: Per USP <795>, there must be "written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed."*** ***If the pharmacy does not transport CNSPs, inspector should answer statement as N/A.***		SOP A-6020 Non-Sterile Compounding Written Control Procedures and Guidelines; page 341	11, 13.2

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
1.14	**Recalls:** The pharmacy has an SOP describing minimum requirements for recalls. ***Inspector note: Per USP, "The facility must have procedures in place to:*** ***- Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, strength, purity, or other quality attributes)*** ***- Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy*** ***- Investigate if other lots are affected and recall if necessary*** ***An SOP for recall of dispensed CNSPs must contain:*** ***- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall*** ***- Procedures to determine the distribution of any affected CNSP, including the data and quantity of distribution*** ***- Procedures to identify patients who have received the CNSP*** ***- Procedures for disposal and documentation of the recalled CNSP (and)*** ***- Procedures to investigate and document the reason for recall."***		SOP A-6020 Non-Sterile Compounding Written Control Procedures and Guidelines; page 343	12.1
	Designated Person(s) and Personnel Training Program **Inspector must complete the <795> Records Review module to complete this section.**			
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."*** ***If no, go to compliance statements.***	Yes		1.1.4

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		1.1.4, 12
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented. ***Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program... The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed."***	Yes		1.1.4, 12
2.3	The designated person(s) is responsible for overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs.	Yes		1.1.4, 2
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.	Yes		1.1.4, 6.2.1
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.	Yes		1.1.4
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.	Yes		1.1.4, 11

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
2.7	The designated person(s) is responsible for establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs.	Yes		1.1.4
3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? ***Inspector note: Per USP, "Training and competency of personnel must be documented."*** ***Inspector is to review a minimum of five personnel records and document their observations (see <795> Records Review module).*** ***If no, go to compliance statements.***	No		2, 14
3.1	All personnel who compound CNSPs have been initially trained and qualified before being allowed to independently compound (eg, perform their job functions). ***Inspector note: Per USP, compounding personnel are defined as "Personnel trained to compound or oversee compounding of preparations."*** ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	No		2, 14
3.2	All personnel who have direct oversight, perform in-process checks, final verification of a CNSP, and/or dispense a CNSP have been initially trained and qualified (according to SOPs) being allowed to independently perform their job functions. ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	No		2, 14

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. ***Inspector note: Per USP, "Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs must undergo training as required by the facility's SOPs."*** ***If questions 2.0-2.12 in the records review tab for compounding personnel or personnel who have direct oversight over compounding personnel are answered "no" or "missing," this statement should be answered no. For details, see the Records Review module.***	Yes		2, 14
4.0	Does the designated person(s) have a documented (periodic) evaluation of their direct observations for compounding activities and documentation of any deficiencies in the record? ***Inspector note: Per USP, this is a recommendation, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*** ***Inspector should complete the <795> Records Review module question 3.0.***	Yes	The DP training is signed off by the PIC and the direct supervisor.	2, 14
	Compounding Personal Hygiene and Garbing			
5.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
5.1	Compounding personnel are required to report to the designated person(s)conditions that may contaminate the compounding preparation area. ***Inspector note: Per USP <795>, examples of conditions that have a higher risk of contaminating the CNSP include: rashes, recent tattoos, open sores, conjunctivitis, and active respiratory infection.***	Yes		
5.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in the compounding areas before their conditions have resolved.	Yes		3
5.3	Personnel removes any unnecessary items (outer garments, jewelry that could interfere with garbing, and earbuds/headphones) before entering the compounding area. ***Inspector note: Inspector should also observe compounding area to identify any items stored that do not belong (ie, dirty garments, jackets, or electronics).***	Yes		3.1
5.4	If personnel do not remove an item, the designated person has determined that the quality of the environment and CNSPs are not adversely affected by the accommodation.	N/A		3.1
6.0	Do personnel perform hand hygiene, wear required garb and gloves, and follow requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3
6.1	All personnel entering the compounding area complete hand hygiene procedures.	Yes		3.2 Box 1

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
6.2	Garb is used for all compounding activities. ***Inspector note: Per USP <795>, gloves are mandatory garb for all compounding activities.***	Yes		3.2, 3.3 Box 1
6.3	Pharmacy uses SDS to determine other garb requirements for the components and compounding activity.	Yes		3.3
6.4	Additional garb (shoe covers, hair and facial hair covers, face masks, gowns) is worn as needed for protection of the personnel/CNSPs. ***If no, please list the garb worn for the type of component and compounding activity.***	Yes		3.3
6.5	The garb purchased by the pharmacy is appropriate for the type of compounding being performed.	Yes		3.3
6.6	Garb is stored in manner that minimizes risk of contamination (away from sinks to avoid splashing, etc).	Yes		3.3
6.7	Gowns that are reused do not leave the compounding area.	Yes		3.3
6.8	Visibly soiled garb or garb with tears or punctures are changed immediately (are not reused).	Yes		3.3
6.9	Soiled garb is disposed of or sent for laundering.	Yes		3.3

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
6.10	Shoe covers, hair and facial hair covers, face masks, and head covers are not reused once personnel have left the compounding area.	Yes		3.3
7.0	Are non-disposable garb such as goggles cleaned then sanitized with 70% isopropyl alcohol before re-use?	N/A		3.3
	Buildings and Facilities			
8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.1
8.1	The pharmacy has a designated compounding space for nonsterile compounding.	Yes		4.1
8.2	The compounding area is well lit.	Yes		4.1
8.3	The compounding area is clean and sanitary.	Yes		4.1
8.4	The compounding area is orderly (eg, clutter free, no tripping hazards).	Yes		4.1
8.5	The compounding area is in a good state of repair.	Yes		4.1

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix- ups among components, containers, labels, in-process materials, and finished CNSPs.	Yes		4.1
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.	Yes		4.1
8.8	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.	Yes		4.1
9.0	Is the compounding area free of carpet?	Yes		4.1
10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.2
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open. ***Inspector note: Per USP, "Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components."*** ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes		4.2

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
10.2	The pharmacy's temperature monitoring records are readily retrievable. ***Inspector note: Per USP, "The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable."***	Yes		4.2
10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Per USP, "All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." USP reports that these devices may be verified against a calibrated device.*** ***Monitoring devices are typically calibrated or replaced.***	Yes		4.2
10.4	Pharmacy has a process to evaluate temperature excursions. ***Inspector note: Per USP, "When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised and if so, the CNSP or component must be discarded."***	Yes		4.2
10.5	CNSPs, components, equipment, and containers are stored off the floor.	Yes		4.2
10.6	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).	Yes		4.2
10.7	CNSPs, components, equipment, and containers are stored in a clean environment (free of dirt, dust, and debris, and rodent/pest/insect free) to prevent contamination.	Yes		4.2

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
11.0	What is the current temperature of the nonsterile compounding storage area? ***Record in the Inspector Notes.***		Temperature of the compounding area at the time of inspection was 69.6°F.	4.2
12.0	Are plumbing fixtures, water sources, and cleanliness of sink in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.3
12.1	The pharmacy staff can easily access a sink within or nearby the nonsterile compounding area.	Yes		4.3
12.2	There is hot and cold running water available at the sink within or nearby the nonsterile compounding area.	Yes		4.3
12.3	The sink is emptied of all items unrelated to compounding and before being used to clean any equipment used in nonsterile compounding.	Yes		4.3
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).	Yes		4.3
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.	Yes		4.3
13.0	Is purified water, distilled water, or reverse osmosis water used for rinsing equipment and utensils used in nonsterile compounding? ***Inspector note: This is a USP recommendation.***	Yes	Distilled water is used.	4.3 USP <1231>

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
	Cleaning and Sanitizing			
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? ***Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues."*** ***List the agents in the Inspector Notes.***		Sanitizing agent used is 91% IPA. The site does not have a cleaning agent in use. The pharmacy does have PREempt wipes, but is not using them in the nonsterile compounding area.	5
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? ***Review compounding cleaning logs.*** ***If no, go to compliance statements.***	No	The site does not have a cleaning agent.	5 Table 1
15.1	All work surfaces are cleaned and sanitized at the **beginning of each shift** on days when compounding occurs.	No		5 Table 1
15.2	All work surfaces are cleaned and sanitized at the **end of each shift** on days when compounding occurs.	No		5 Table 1
15.3	All work surfaces are cleaned and sanitized **between compounding CNSPs with different components**.	No		5 Table 1
15.4	Floors are cleaned and sanitized daily on days when compounding occurs.	No		5 Table 1

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. ***Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.***	No		5 Table 1
15.6	All work surfaces, floors, walls, ceilings and storage shelving are cleaned and sanitized when surface contamination (eg, splashes) or spills are known or suspected.	No		5 Table 1
15.7	Storage shelving is cleaned and sanitized at least every three months.	No		5 Table 1
16.0	Are floors in the compounding area easily cleanable, non-porous, and non-particle generating? ***Inspector note: This is a USP recommendation. Per USP, "Surfaces should be resistant to damage by cleaning and sanitizing agents."***	Yes		5
	Equipment and Components FDA defines manufacturer... as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes the activities of relabelers, repackers, and salvagers. When not modified by "domestic" or "foreign," the term includes both domestic manufacturers and foreign manufacturers.			
17.0	Does the pharmacy use a closed-system processing device (eg, CVE, BSC, and single-use containment glove bags)? ***Inspector note: Per USP, examples of closed-system processing devices include: containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags.*** ***If yes, list the type(s) in the Inspector Notes.***	No		6.1

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? ***Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or sorptive, and must not alter the quality of CNSPs."*** ***Review certification reports, calibration records, and cleaning logs.*** ***If no, go to compliance statements.***	No		6.1
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs prepared. ***Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.***	Yes		6.1
18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. ***Inspector note: Per USP, "components that could generate airborne chemical particles (eg, active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs."*** ***If no, inspector should describe observations.***	Yes		6.1

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. ***Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation." Additionally, per Table 2:*** ***- CVE/BSC are cleaned and sanitized at the beginning and end of each shift when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected;*** ***- CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;*** ***- Under the work surface of a BSC is cleaned and sanitized at least monthly; and*** ***- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.*** ***If no, inspector should describe observations.***	No	Clean equipment is stored next to the sink without any protective covering or barrier once cleaned.	6.1 Table 2
18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). ***Inspector note: For example, the pharmacy may need to tare a scale and/or balance prior to use.***	Yes		6.1
18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent). ***If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as ones needed for weighing or measuring), the inspector should answer this statement as N/A.***	N/A	No scales or mechanical devices are used for compounding.	6.1

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. ***If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the inspector should answer this statement as no. If the pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.***	N/A		6.1
19.0	Does the pharmacy compounding CNSPs use APIs?	No		6.2
20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? ***Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.*** ***If no, go to compliance statements.***	N/A		6.2.1
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. ***If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.***	N/A		6.2.1
20.2	All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that the test results for the component show the API meets expected quality. ***Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay has been performed and will include water content (so any corrections/calculations can be performed).***	N/A		6.2.1

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
20.3	All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. Inspector should verify the pharmacy looks up the name of the manufacturer listed on the COA to determine if they are registered as an FDA drug establishment https://dps.fda.gov/decrs.***	N/A		6.2.1
21.0	When formulations indicate the inclusion of water, is purified water or better quality (eg, sterile water for irrigation) used in compliance with USP <795> standards?	No	Distilled water is used for compounding.	6.2.1
22.0	What type(s) of water is used for compounding CNSP? ***List the type(s) in the Inspector Notes.***		Distilled water is used for compounding.	6.2.1
23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? ***If no, go to compliance statements.***	N/A		6.2.2
23.1	For non-conventionally manufactured components, the COA is reviewed upon receipt. ***Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists." Pharmacy's review should be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify the COA is retrievable.***	N/A		6.2.2

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
23.2	The pharmacy documents specific information according to the facility's SOP, including: receipt date, quantity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).	N/A		6.2.2, 14
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaging system received the date the component must no longer be used by the pharmacy. ***Inspector note: Per USP, "Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations 797 , 9.3.2 Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation."***	N/A		6.2.2
23.4	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	N/A		6.2.2
23.5	Any other lots of that (rejected) component from that vendor are examined to determine whether other lots have the same defect.	N/A		6.2.2
24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? ***If no, go to compliance statements.***	N/A		6.2.3, 6.2.4

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
24.1	Compounding personnel visually re-inspect each component, including packaging system (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have changed during storage).	N/A		6.2.3
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.	N/A		6.2.3
24.3	Components where correct identity, strength, purity, and quality cannot be confirmed (eg, containers with damaged or incomplete labeling), are immediately rejected and if not immediately discarded, labeled as rejected and segregated from active stock.	N/A		6.2.3
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and laws/regulations of the applicable regulatory jurisdiction.	N/A		1.1.3, 6.2.4
24.5	All components are handled in a manner that minimizes the risk of contamination, mix-ups, and deterioration.	N/A		6.2.4
25.0	When components are removed from the original container and not used in compounding (eg, excess after weighing), are they discarded and not returned to the original container (to minimize risk of contamination of the original component container)? ***Inspector note: This is a USP recommendation.***	N/A		6.2.4

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.5
26.1	Pharmacy staff have access to safety data sheets (SDS).	Yes		6.2.5
26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.	Yes		6.2.5, 14
26.3	The pharmacy has a readily accessible spill kit in the compounding area.	Yes		6.2.5
26.4	The pharmacy has a process to manage and document any nonhazardous spills and disposal.	Yes		6.2.5
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.5
	Master Formulation Records (MFR) and Compounding Records (CR) **Inspector should review a minimum of five (5) MFRs and five (5) CRs.**			
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? ***Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.*** ***If no, go to compliance statements.***	Unknown		7.1

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
27.1	An MFR is created for each unique formulation.	Yes		7.1 Box2
27.2	Any changes or alterations to the MFR are approved and documented.	Yes		7.1
27.3	Does the designated person(s) or designee evaluate CNSP's characteristics when considering the assigned BUD for an MFR? ***Inspector note: Per USP, "When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following:*** ***- Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)*** ***- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)*** ***- Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP*** ***- Potential for microbial proliferation in the CNSP (and)*** ***- Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation."***	Unknown	References for the BUD assignment are not USP. References used for BUD assignment include "Part 1 Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients. Third Edition". It is unknown if the specific components required by the referenced BUD assignments are the specific manufactures NDC#s, containment closure device(s), or specific instructions for compounding.	7.1, 10.2 Table 4
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.***	Unknown		7.1

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.1
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (eg, particle size, salt form, purity grade, solubility).	Yes		7.1
28.3	MFR includes the type of container–closure system(s).	Yes		7.1
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. ***Inspector note: Per USP, the MFR will also include, "Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure repeatability include, but are not limited to: speed duration, settings on equipment, and specific order of mixing (if applicable).*** ***Inspector should review several MFRs for completeness of instructions.***	Yes		7.1
28.5	MFR has a physical description of the final CNSP.	Yes	Binder of MFRs were out of date and did not have physical descriptions, but the electronic forms have been updated with a physical description.	7.1
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.	Yes		7.1

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
28.7	MFR contains the reference source to support the assigned BUD.	Unknown	References for the BUD assignment are not USP. References used for BUD assignment include "Part 1 Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients. Third Edition". It is unknown if the specific components required by the referenced BUD assignments are the specific manufactures NDC#s, containment closure device(s), or specific instructions for compounding.	7.1
28.8	Labeling requirements (eg, shake well) are described on the MFR.	Yes		7.1
28.9	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.	N/A		7.1
28.10	An MFR has QC procedures (eg, pH testing, visual inspection) and expected results.	Yes		7.1
29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).***	No		7.2, 14

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
29.1	A CR is completed for each CNSP prepared.	Yes		7.2, 14
29.2	The CR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.2, 14
29.3	The CR includes the date (or date and time) the CNSP was prepared.	No	Time was not filled in on reviewed record for C-Losartan 2.5 mg / mL Suspension CR for 2 compounding records. There is a space to put the time of compounded but the field was not populated with the time compounded.	7.2, 14
29.4	The CR includes the assigned internal identification number (eg, prescription, order, or lot number).	Yes		7.2, 14
29.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.	Yes		7.2, 14
29.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.	Yes		7.2, 14
29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component.	Yes		7.2, 14
29.8	The CR includes the weight or measurement of each component.	Yes		7.2, 14
29.9	The CR identifies the total quantity compounded.	Yes		7.2, 14

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
29.10	The CR lists the assigned BUD and storage requirements.	Yes		7.2, 14
29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API.	N/A		7.2, 14
29.12	The CR has a physical description of the final CNSP.	Yes		7.2, 14
29.13	The CR includes the results of quality control procedures (eg, pH testing, visual inspection).	Yes		7.2, 14
29.14	The CR contains a MFR reference for the CNSP.	Yes		7.2, 14
29.15	Each CR is reviewed for completeness before the CNSP is released.	Yes		7.2, 8
29.16	The CR shows traceability of all components in the case of a recall or known quality issue.	Yes		7.2, 12.1, 14
30.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks indicate that appropriate procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation.*** ***Inspector should describe their observations in the Inspector Notes .***	Yes	Pharmacist conducts an in-process check of components, quantities, and measurements prior to compounding. A post compounding check process is conducted at time of labeling.	2, 7.2, 8

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
	Labeling			
31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		9
31.1	Information on the label is prominently and legibly displayed. ***Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container."***	Yes		9
31.2	The labeling meets any state or federal regulatory requirements.	Yes		1.1.3, 9
31.3	The label on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		9
31.4	The label on the immediate container includes the active ingredients and their amount(s), activity(ies), or concentration(s).	Yes		9
31.5	The label on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		9
31.6	The label on the immediate container includes the BUD. ***If no, please describe whether the pharmacy instead used the term "expiration date" or similar language or if this information was not included on the label.***	Yes	A "Discard After" ancillary label with the calculated BUD is applied to the bottle.	9

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
31.7	The label on the immediate container includes the dosage form.	Yes		9
31.8	The label on the immediate container includes the total amount or volume, if it is not obvious from the container.	Yes		9
32.0	Does the labeling on the dispensed CNSP include the route of administration? ***Inspector note: This is a USP recommendation.***	Yes		9
33.0	Does the labeling contain information identifying the CNSP as a compounded preparation? ***Inspector note: Per USP, this is a recommendation.***	Yes		9 USP <7>
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? ***Inspector note: This is a USP recommendation.***	Yes		9
35.0	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CNSP was to be sent outside of the facility or health care system? ***Inspector note: This is a USP recommendation.*** ***If the pharmacy only compounds CNSPs for patient use onsite (eg, a health care facility), inspector should answer this question as N/A .***	Yes		9

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
	Establishing Beyond Use Dating (BUDs)			
36.0	Is each CNSP assigned and labeled with a BUD in compliance with USP <795> standards? ***Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date."*** ***If no, go to compliance statements.***	Unknown	References for the BUD assignment are not USP. References used for BUD assignment include "Part 1 Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients. Third Edition". It is unknown if the specific components required by the referenced BUD assignments are the specific manufactures NDC#s, containment closure device(s), or specific instructions for compounding.	10 USP <7>
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and must be discarded.	Yes	Ancillary label is added to compound with a "Discard After" date that is calculated by the pharmacy technician and verified by a pharmacist.	10.1
36.2	CNSP labels do not list an "expiration date" or equivalent language.	Yes		10.1
36.3	BUDs are assigned from the date (and time) of preparation.	Yes		10.1
36.4	BUDs are assigned based on dispensing in tight, light resistant containers/overpacks. ***Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply."***	Yes		10.3

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.	Yes		10.4
37.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest BUD of any individual compounded components? ***Inspector note: Per USP, "For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CNSP must not be negatively impacted." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see are stock solutions (and other formulas within a formula) such as methocel 1%.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		10.4
38.0	Does the designated person(s) evaluate a CNSP formulation to establish the maximum BUD? ***If no, who establishes the maximum BUD for a MFR?***	Yes	The DP defines the BUDs for the MFRs.	7.1, 10.2, 10.3
39.0	Does the pharmacy compound CNSPs with a USP monograph?	No		10.5
40.0	Does the pharmacy compound CNSPs following the USP monograph precisely? ***If no, go to compliance statements.***	N/A		10.5

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
40.1	Pharmacy staff have access to the USP monograph for reference.	N/A		10.5
40.2	CNSPs are prepared in accordance with the USP monographs. ***If no, inspector to collect a copy of the compounding record, label; and describe what specific steps of the monograph were not followed.***	N/A		10.5
40.3	Components used by the compounder match those listed in the monograph. ***If no, describe the source of the component in monograph and the source that the pharmacy used.***	N/A		10.5
40.4	The maximum BUD specified in the USP monograph is not exceeded. ***If no, identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.***	N/A		10.5
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?	Yes		10.4

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
42.0	Does the pharmacy adhere to the BUD (maximum) limits established in Table 4 for CNSPs in compliance with USP <795> standards? ***Inspector note: This question is for the CNSPs compounded that are not following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has completed or has access to CNSP-Specific Stability Information). Per USP, the pharmacy is not required to measure water activity (A_w) for a CNSP.*** ***If no, go to compliance statements.*** ***If all CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.***	Unknown	References for the BUD assignment are not USP. References used for BUD assignment include "Part 1 Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients. Third Edition". It is unknown if the specific components required by the referenced BUD assignments are the specific manufactures NDC#s, containment closure device(s), or specific instructions for compounding.	10.4
42.1	**Non-preserved, Aqueous Dosage Forms**: The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	No	References for the BUD assignment are not USP. References used for BUD assignment include "Part 1 Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients. Third Edition". It is unknown if the specific components required by the referenced BUD assignments are the specific manufactures NDC#s, containment closure device(s), or specific instructions for compounding.	10.4 Table 4 USP <659>

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
42.2	**Preserved, Aqueous Dosage Forms:** The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>
42.3	**Nonaqueous, Oral Liquid Dosage Forms:** The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have a A_w < 0.6. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspension.*** ***If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
42.4	**Nonaqueous Dosage Forms:** The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous (Solid) dosage forms are ones that have a A_w < 0.6. Some examples include capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.*** ***If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the maximum limits in Table 4 USP <795>?	Yes	References for the BUD assignment are not USP. References used for BUD assignment include "Part 1 Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients. Third Edition". It is unknown if the specific components required by the referenced BUD assignments are the specific manufactures NDC#s, containment closure device(s), or specific instructions for compounding.	10.5 Table 4
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? ***If no, go to compliance statements.***	Unknown		10.5

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
44.1	The labeled BUD for an aqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	Yes		10.5
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	Yes		10.5
44.3	Pharmacy is following the results of their own stability study. ***If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A.*** ***If pharmacy is following a bracketed study, inspector may mark this statement as yes if concentrations of CNSPs are at or within the concentrations specified within the study.*** ***If pharmacy is following a bracketed study and is using a concentration outside the study, answer this question as a no and describe observations.***	N/A		10.5
44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method, for extending BUDs. ***Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	No	References for the BUD assignment are not USP. References used for BUD assignment include "Part 1 Extemporaneous Formulations for Pediatric, Geriatric, and Special Needs Patients. Third Edition". It is unknown if the specific components required by the referenced BUD assignments are the specific manufactures NDC#s, containment closure device(s), or specific instructions for compounding.	10.5

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
44.5	The cited stability study (which uses a stability-indicating analytical method for extending BUDs) describes the API(s), CNSP formulation, and material composition of the container closure used. ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	Unknown		10.5
44.6	If the cited stability study (which uses a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. ***If no, describe the concentrations cited in the stability study and the concentration of the CNSP compounded by the pharmacy.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.***	Unknown		10.5
44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4, have: - been tested for antimicrobial effectiveness at least once for each formulation in the type of (with the same material composition of the) container closure system that will be used; - received study results from an FDA-registered facility (for the same CNSP formulation using the same material composition of the container closure system); or - a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system). ***Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information includes the low and high concentration of each active ingredient in the formulation. Per USP, this is "to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.***	Unknown		10.5

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
	Quality Assurance (QA), Quality Control (QC), and Quality Management (QM) Inspector to review at least one complaint, one adverse event, and one recall (if applicable).			
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? ***If no, go to compliance statements.***	Yes		1.1.3, 12
45.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction."***	Yes		12
45.2	The QA/QC programs address adherence to procedures.	Yes		12
45.3	The QA/QC programs address prevention and detection of errors and other quality problems.	Yes		12
45.4	The QA/QC programs address evaluation of complaints and adverse events. ***Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.***	Yes		12
45.5	The QA/QC programs address appropriate investigations and corrective actions.	Yes		12

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
46.0	Has the pharmacy received any complaints related to CNSPs within the past year?	No		12
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.2
47.1	The pharmacy has a complete written or electronic record of each complaint made. ***Inspector note: Per USP, "The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained."***	Yes		12.2
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.	Yes		12.2
47.3	Complaints are reviewed to determine whether it indicates a potential quality problem with the CNSP.	Yes		12.2
47.4	Complaints are fully investigated.	Yes		12.2

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
47.5	Complaint investigations consider whether the quality problem extends to other CNSPs.	Yes		12.2
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. ***Inspector note: Per USP, the pharmacy is to, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."***	Yes		12, 14
47.7	A CNSP that is returned in connection with a complaint is quarantined until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.	N/A		1.1.3, 12.2
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? ***Inspector note: Per USP <795> requires all records to be readily retrievable for two years, including recalls; However, the state/jurisdictional regulator may require records to be kept for a longer period of time.*** ***Review most recent recall and describe in the Inspector Notes.*** ***If the pharmacy has not had any recalls within the past two years, inspector should answer the question as No.***	No		12.1, 14
49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.1, 12.2, 12.3

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
49.1	The pharmacy has procedures to determine when recalls must be initiated.	Yes		12.1
49.2	The pharmacy documents the implementation of the recall.	Yes		12.1
49.3	Pharmacy reports recalled CNSPs to the appropriate regulatory bodies (as required by laws and regulations of the applicable regulatory jurisdiction).	Yes		1.1.3, 12.1
49.4	Investigations into an adverse event that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.	Yes		12.3
50.0	Does the pharmacy procedures include a step to immediately notify the prescriber of a failure of specifications with potential to cause harm (eg, strength, purity, or other quality attributes)? ***Inspector note: This is a USP recommendation.***	Yes		12.1
	CNSP Packaging			
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? ***If no, go to compliance statements.***	Yes		13.1
51.1	The packaging materials protect CNSPs from damage, leakage, contamination, and degradation.	Yes		13.1
51.2	The packaging materials used protects personnel from exposure (from the packaged CNSP).	Yes		13.1
52.0	The packaging materials selected by the pharmacy maintain the physical and chemical integrity and stability needed for CNSPs (eg, protect from light).	Yes	SOP Shipping Packout Procedure Audit outlines the testing of shipping materials.	13.1

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
	Compounding Personnel Observations - *Inspector must observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. It is acceptable for pharmacy staff to perform mock compounding activities (with two creams or other drugs) as long as all observations can be viewed.*			
53.0	**Personal Preparation Observation:** Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		
53.1	Personnel removed all outer garments (eg, hats, scarves, bandanas, vests, coats, and jackets).	Yes		3.1
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.	Yes		3.1
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (eg, watches, rings that may tear gloves).	Yes		3.1
53.4	Personnel removed earbuds or headphones.	Yes		3.1
53.5	Any accommodations permitted by the designated person(s) should be documented. ***Inspector note: Per USP <795>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	N/A		3.1

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
54.0	**Hand Hygiene Observation:** Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.2, Box 1
54.1	All personnel who enter the compounding area to compound performed hand hygiene.	Yes		3.2 Box 1
54.2	Personnel wash hands with soap and water for at least 30 seconds.	Yes		3.2
54.3	Personnel dry their hands completely with disposable towels or wipers.	Yes		3.2
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.	Yes		3.2
55.0	***Garbing Observation:*** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3 Box 1
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3 Box 1
55.2	All personnel who perform compounding activities don gloves. ***Inspector note: Per USP, "Gloves must be worn for all compounding activities."***	Yes		3.2, 3.3 Box 1

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.	Yes		3.3 Box 1
56.0	Are gloves wiped or replaced before beginning compounding a CNSP with a different component or when other objects were touched (eg, pens, keyboards) to minimize risk of cross contamination with other CNSPs? ***Inspector note: This is a USP recommendation.***	Yes		3.3
57.0	List the name(s) of the CNSPs observed by the inspector as part of live compounding demonstration.		Mock Compound for Inspector: Aspirin 5.4 mg / mL oral suspension; 60 mL	
58.0	**Compounding Observation:** Are compounding personnel using appropriate nonsterile compounding techniques for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	No		2 Box 3
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOPs.	Yes		3.1, 4.1
58.2	The compounding personnel started with a clean compounding area for CNSPs.	Yes		4.1, 4.3, 5 Table 1
58.3	The compounding personnel selected the correct MFR for the CNSP to be prepared.	Yes		7, 7.1 Box 2

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
58.4	The compounding personnel performed hand hygiene. ***Inspector note: Per USP <795>, Box 1, personnel are to: wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.***	Yes		3.2 Box 1
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.	Yes		3.3
58.6	The compounding personnel obtained the proper ingredients (APIs and/or components). ***Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.***	Yes		6.2 (6.2.1 - 6.2.5)
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR and is in good working order prior to use for the CNSP. ***Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (eg, tare scales and/or balances).***	Yes		6.1 Table 2
58.8	The compounding personnel have knowledge of and access to any SDS.	Yes		6.2
58.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).	Yes		1.1.3

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
58.10	The compounding personnel compound the CNSP according to the MFR. ***If no, inspector needs to describe in detail their observations in the Inspector Notes and collect a copy of the MFR and CR (no PHI or PII to be collected).***	Yes		7.1, 7.2 Box 2
58.11	The compounding personnel document any required steps listed in the MFR on the CR. ***Inspector note: This would include any weights, volume, and any in-process checks needed.***	Yes		7.2, 14 Box 3
58.12	Documentation in the CR is legible. ***If no, collect copy of record that is illegible. Redact any PHI on record.***	Yes		14
58.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.	Yes		10 Table 3, Table 4
58.14	The compounding personnel performed any quality control steps specified in the MFR. ***Inspector note: Examples of this include, but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.*** ***If no, describe observations in Inspector Notes.***	Yes		7.2, 8, 8.1, 12 Box 3
58.15	The compounding personnel placed the CNSP into the proper container closure system.	Yes		8.1 Box 2
58.16	The compounding personnel labeled the CNSP. ***Inspector note: Storage requirements must be included on the label if refrigerated or frozen (so patient can identify the storage temperature requirements).***	Yes	Verbalized by the pharmacy technician.	9

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
58.17	The compounding personnel completed any documentation on the CR. ***If no, describe observations of what was missing or omitted in Inspector Notes.***	Yes		7.2, 8, 14 Box 3
58.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.	No	In accordance to SOP, as noted only 91% IPA is used. This is only a sanitizing agent.	5
59.0	**Final CNSP check observation**: Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? ***Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs release inspection observed in the Inspector Notes.*** ***If no, go to compliance statements.***	Yes		8, 8.1, 9
59.1	CNSP was visually inspected to determine the physical appearance of the CNSP is as expected (eg, color, texture, physical uniformity), including any special characteristics listed in the MFR (eg, emulsions must be checked for phase separation).	Yes		8, 8.1
59.2	Visual inspection included checking for container closure integrity (eg, leakage, cracks, improper seals).	Yes		8, 8.1
59.3	CNSP label was verified against the prescription or medication order.	Yes		8, 8.1, 9
59.4	CNSP label was verified against the MFR.	Yes		8, 8.1, 9

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
59.5	CNSP label was verified against the CR.	Yes		8, 8.1, 9
59.6	If a CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.	Yes		8, 8.1
59.7	All checks and inspection that are performed are properly documented.	Yes		8.1, 14
59.8	CNSP that do not meet requirements, are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal	Yes		8.1
60.0	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately.*** ***Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, particulates, dirt/debris/(suspected) mold within container closure); number of preparations affected (eg, two of the five containers on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	N/A	There are no CNSPs on site for the inspector to inspect. CNSPs are prepared and shipped as they are ordered.	12

Copyright© July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization

National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Amber Enterprises, Inc. dba Amber Specialty Pharmacy
e-Profile ID: 787800
Inspection Date: 10/09/2025 & 10/14/2025

		Observation	Inspector Notes	USP Reference(s)
61.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standards? ***Document observations while pharmacy staff are performing live compounding activities in Inspector Notes.*** ***If no, go to compliance statements.***	No	Only sanitization with 91% IPA.	5
61.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.	No	They perform sanitization prior to compounding a CNSP.	5 Table 1
61.2	Pharmacy staff perform cleaning and sanitizing between compounding CNSPs with different components. ***Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."***	No	Only sanitization with 91% IPA.	5 Table 1
61.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross contamination of the next preparation).	No	They perform this sanitization only.	6.1 Table 2
61.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.	No	They perform this sanitization only.	5 Table 1

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Nonsterile <795> Employee File Records Review

Select the PIC, designated person, a staff pharmacist that checks compounded preparations, and two to three compounding pharmacy technicians. *Do not record the employee name, list only their title or position.
From the drop-down List:
*Mark as "Yes" if the document is present in the records and the competency evaluation was conducted in compliance with USP <795> requirements.
*Mark as "No" if the document is present in the records but is not in compliance with USP <795> requirements.
*Mark as "Missing" if any part of the record is missing and explain in Notes column.
*Mark as "N/A" if the training does not apply (eg, long-term employee may not have initial training available). Document further in the Notes column.

		Employee Records #1	Employee Records #2	Employee Records #3	Employee Records #4	Employee Records #5	
	Employee Title	**Pharmacist**	**Pharmacy Technician**	**Pharmacy Technician**	**Pharmacist**	**Pharmacy Technician**	**Notes**
1.0	The training program provides initial training, evaluation, and documentation on the core competencies listed below:						
1.1	Compounding personnel are trained on facility SOPs.	Yes	Yes	Yes	Yes	Yes	
1.2	Compounding personnel are trained on USP <795> standards.	Yes	Yes	Yes	Yes	Yes	
1.3	The training record for hand hygiene is complete.	Yes	Yes	Yes	Yes	Yes	
1.4	The training record for garbing is complete.	Yes	Yes	Yes	Yes	Yes	
1.5	The training record for cleaning and sanitizing is complete.	Yes	Yes	Yes	Yes	Yes	
1.6	The training record for handling and transporting components and CNSPs is complete.	Yes	Missing*	Missing*	Yes	Missing*	*Prior to change to USP <795>
1.7	The training record for measuring and mixing is complete.	Yes	Yes	Yes	Yes	Yes	
1.8	The training record for proper use of equipment is complete.	Yes	Yes	Yes	Yes	Yes	
1.9	The training record for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Yes	Yes	Yes	Yes	

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

	Employee Title	Pharmacist	Pharmacy Technician	Pharmacy Technician	Pharmacist	Pharmacy Technician	Notes
1.10	The training record for interpreting a Certification of Analysis (COA) is complete.	Yes	Yes	Yes	Yes	Missing	Noted missing on historical staff, but the initial training form has been updated.
1.11	The training record for how to read/interpret a Safety Data Sheet (SDS) is complete.	Yes	Yes	Yes	Yes	Missing	
1.12	The training record for spill management is complete.	Yes	Yes	Yes	Yes	Yes	
2.0	The annual competency assessment was evaluated and documented on the following topics:						
2.1	Compounding personnel are re-trained on facility SOPs.	Yes	Yes	Yes	Yes	Yes	
2.2	Compounding personnel are re-trained on USP <795> standards.	Yes	Yes	Yes	Yes	Yes	
2.3	The annual competency assessment for hand hygiene is complete.	Yes	Yes	Yes	Yes	Yes	
2.4	The annual competency assessment for garbing is complete.	Yes	Yes	Yes	Yes	Yes	
2.5	The annual competency assessment for cleaning and sanitizing is complete.	Yes	Yes	Yes	Yes	Yes	
2.6	The annual competency assessment for handling and transporting components and CNSPs is complete.	Yes	Yes	Yes	Yes	Yes	
2.7	The annual competency assessment for measuring and mixing is complete.	Yes	Yes	Yes	Yes	Yes	
2.8	The annual competency assessment for proper use of equipment is complete.	Yes	Yes	Yes	Yes	Yes	
2.9	The annual competency assessment for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Yes	Yes	Yes	Yes	
2.10	The annual competency assessment for interpreting a COA is complete.	Yes	Yes	Yes	Yes	Yes	

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

	Employee Title	Pharmacist	Pharmacy Technician	Pharmacy Technician	Pharmacist	Pharmacy Technician	Notes
2.11	The annual competency assessment for how to read/interpret a SDS is complete.	Yes	Yes	Yes	Yes	Yes	
2.12	The annual competency assessment for spill management is complete.	Yes	Yes	Yes	Yes	Yes	
3.0	The designated person(s) has documented a (periodic) evaluation of their direct observations for compounding activities and documented any deficiencies in the record. *Inspector note: if there are not observations documented, the inspector should answer this question as N/A. Per USP, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*	Yes	Yes	Yes	Yes	Yes	The DP has signed off on all the compounding staff.

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Glossary & References	USP <795>
Active Pharmaceutical Ingredient (API)	Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as a bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added Substance	An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with inactive ingredient, excipient, and pharmaceutical ingredient.
Administration	The preparation of a nonsterile pharmacologic or other therapeutic agent for ingesting, inserting, applying, or otherwise providing a nonsterile medication in its final form to a single patient. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids to facilitate patient dosing.
Alcohol-based hand rub	An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Assigned trainer	One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CNSPs.
Beyond-use date (BUD)	The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.
Biological Safety Cabinet (BSC)	A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
Bulk drug substance	See the entry for Active Pharmaceutical Ingredient.
Certificate of analysis (COA)	A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
Cleaning	The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleaning agent	An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Closed-system processing device	A device designed to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples include CVEs, BSCs, or single-use containment glove bags.

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Glossary & References	USP <795>
Component	Any ingredient used in the compounding of a preparation, including any API, added substance, or conventionally manufactured product.
Compounded nonsterile preparation (CNSP)	A preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance.
Compounding	The process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.
Compounding area	An area that is specifically designated for nonsterile compounding.
Compounding personnel	Personnel trained to compound or oversee compounding of preparations.
Compounding record (CR)	Documents the compounding of each CNSP.
Container closure system	Packaging system components that together contain and protect the dosage form. This includes primary packaging system components and secondary packaging system components if the latter are intended to provide additional protection.
Containment glove bag	A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE)	A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
Conventionally manufactured product	A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Designated person(s)	One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs.
FDA	US Food and Drug Administration
Formulation	The specific qualitative and quantitative composition of the final CNSP.
Hazardous Drug (HD)	Any drug identified by at least one of the following criteria: carcinogenicity, teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low dose in humans or animals; genotoxicity or new drugs that mimic existing HDs in structure or toxicity. See <800>.
Label	The part of the labeling on the immediate container.
Labeling	All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container.

Copyright © July 2024 National Association of Boards of Pharmacy® (NABP®). All rights reserved. NABP developed this inspection form for sole use by NABP, boards of pharmacy, government agencies that regulate drug distributors, and for internal use by the named facility participating in the VPP. Disclosure of this form to a third party or use of the form by a third party is strictly prohibited without NABP's prior written authorization.

Glossary & References	USP <795>
Master formulation record (MFR)	A detailed record of procedures that describes how the CNSP is to be prepared.
Monograph	A quality documentary standard within USP–NF that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Oversight	The review, monitoring, and supervision of actions taken by personnel; bearing responsibility for those actions; and being available if and when needed for consultation, even if not physically present.
Preservative	A substance added to inhibit microbial growth.
Purified water	The minimal quality of source water for the production of Purified Water is drinking water whose attributes are prescribed by the US Environmental Protection Agency (EPA), the European Union, Japan, or the World Health Organization (WHO). This source water may be purified using unit operations that include deionization, distillation, ion exchange, reverse osmosis, filtration, or other suitable purification procedures. (See <1231>, 3.1.1 Purified Water.)
Quality Assurance (QA)	A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
Quality Control (QC)	The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met for the CNSP.
Reconstitution	The process of adding a diluent to a conventionally manufactured product to prepare a solution or suspension.
Release inspection and testing	Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Sanitizing agent	An agent for reducing, on inanimate surfaces, the number of microorganisms (eg, 70% isopropyl alcohol).
SDS	Safety data sheet.
SOP	Standard operating procedure.
Specification	The tests, analytical methods, and acceptance criteria to which any components, CNSP, container closure system, equipment, or other material used in the compounding of CNSPs must conform to be considered acceptable for its intended use.
Stability	The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Verify	To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Water activity (a_w)	A measure of the fraction of total water that is unbound and freely available to participate in chemical, biochemical, or physicochemical reactions or provide an environment that can support microbial growth. Note that a_w is not water content.

Pharmacy Name:	Amber Enterprises, Inc dba Amber Specialty Pharmacy
Pharmacy Address:	10004 S 152nd St, Suite A, Omaha, NE 68138
NABP Business e-Profile ID:	787800
VPP Inspection Date(s):	10/14/2025
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	41	3.0	The pharmacy has created and implemented a training program that is in compliance with USP <795> standards.	11/12/2025	N	
Clarification or Further Explanation	41	3.1	The pharmacy has created and implemented a training program that is in compliance with USP <795> standards. Initial training records for some employees pre-dates the current USP <795> standards, but re-training and subsequent annual retraining for these employees meets the current standards. Re-training was conducted at the time of implementation of current USP <795> standars.	11/12/2025	N	
Clarification or Further Explanation	41	3.2	The pharmacy has created and implemented a training program that is in compliance with USP <795> standards. Initial training records for some employees pre-dates the current USP <795> standards, but re-training and subsequent annual retraining for these employees meets the current standards. Re-training was conducted at the time of implementation of current USP <795> standars.	11/12/2025	N	
Clarification or Further Explanation	49	15.0	Company policy requires cleaning sanitizing per USP <795> guidelines Table 1 as included in our company policy and procedure manual. All staff performing non-sterile compounding to be retrained on this policy and requirements.	12/1/2025	N	
Clarification or Further Explanation	49	15.1	Company policy requires cleaning sanitizing per USP <795> guidelines Table 1 as included in our company policy and procedure manual. All staff performing non-sterile compounding to be retrained on this policy and requirements.	12/1/2025	N	
Clarification or Further Explanation	49	15.2	Company policy requires cleaning sanitizing per USP <795> guidelines Table 1 as included in our company policy and procedure manual. All staff performing non-sterile compounding to be retrained on this policy and requirements.	12/1/2025	N	
Clarification or Further Explanation	49	15.3	Company policy requires cleaning sanitizing per USP <795> guidelines Table 1 as included in our company policy and procedure manual. All staff performing non-sterile compounding to be retrained on this policy and requirements.	12/1/2025	N	
Clarification or Further Explanation	49	15.4	Company policy requires cleaning sanitizing per USP <795> guidelines Table 1 as included in our company policy and procedure manual. All staff performing non-sterile compounding to be retrained on this policy and requirements.	12/1/2025	N	
Clarification or Further Explanation	50	15.5	Company policy requires cleaning sanitizing per USP <795> guidelines Table 1 as included in our company policy and procedure manual. All staff performing non-sterile compounding to be retrained on this policy and requirements.	12/1/2025	N	
			Company policy requires cleaning sanitizing per USP <795> guidelines Table 1 as included in our company policy and procedure manual. All staff performing non-sterile compounding to be retrained on this policy and			

This VPP Inspection response and documentation has been provided directly by the phar
response to its VPP Inspection. The content of this response has not been verified or modified
at this point in time, except to check for completeness of any attachments provided.

Pharmacy Name:	Amber Enterprises, Inc dba Amber Specialty Pharmacy
Pharmacy Address:	10004 S 152nd St, Suite A, Omaha, NE 68138
NABP Business e-Profile ID:	787800
VPP Inspection Date(s):	10/14/2025
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	51	18.0	Clean equipment was previously stored on the counter. Clean equipment is now stored in a closed container until use. All staff will be trained on this procedure.	12/1/2025	N	
Clarification or Further Explanation	52	18.3	Clean equipment was previously stored on the counter. Clean equipment is now stored in a closed container until use. All staff will be trained on this procedure.	12/1/2025	N	
Clarification or Further Explanation	54	21.0	As referenced on our master formulation records, sterile water for irrigation is used in all compounds requiring water. Distilled water is only used to rinse clean equipment. This was in place at the time of inspection.	11/12/2025	N	
Clarification or Further Explanation	57	27.0	An MFR is created for each unique formulation of a CNSP. An example has been included for reference.	11/12/2025	Y	Bethanechol 1mg per ML MFR #7 11.12.25
Clarification or Further Explanation	58	27.3	All aquaous formulations have been updated to include BUD of 14 days when refrigerated. An example has been included for reference.	11/12/2025	Y	Bethanechol 1mg per ML MFR #7 11.12.25
Clarification or Further Explanation	58	28.0	All MFRs contain all requirements in compliance with USP 795 standards.	11/12/2025	Y	Bethanechol 1mg per ML MFR #7 11.12.25
Clarification or Further Explanation	60	28.7	All aquaous formulations have been updated to include BUD of 14 days when refrigerated. An example has been included for reference.	11/12/2025	Y	Bethanechol 1mg per ML MFR #7 11.12.25
Clarification or Further Explanation	60	29.0	All staff will be retrained on requirement to add time compounded to CR.	12/1/2025	N	

This VPP Inspection response and documentation has been provided directly by the phar response to its VPP Inspection. The content of this response has not been verified or modified at this point in time, except to check for completeness of any attachments provided.

Pharmacy Name:	Amber Enterprises, Inc dba Amber Specialty Pharmacy
Pharmacy Address:	10004 S 152nd St, Suite A, Omaha, NE 68138
NABP Business e-Profile ID:	787800
VPP Inspection Date(s):	10/14/2025
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	61	29.3	All staff will be retrained on requirement to add time compounded to CR.	12/1/2025	N	
Clarification or Further Explanation	60	28.7	All aquaous formulations have been updated to include BUD of 14 days when refrigerated.	11/12/2025	N	
Clarification or Further Explanation	68	42.0	All aquaous formulations have been updated to include BUD of 14 days when refrigerated.	11/12/2025	N	
Clarification or Further Explanation	68	42.1	All aquaous formulations have been updated to include BUD of 14 days when refrigerated.	11/12/2025	N	
Clarification or Further Explanation	70	43.0	All aquaous formulations have been updated to include BUD of 14 days when refrigerated.	11/12/2025	N	
Clarification or Further Explanation	70	44.0	All aquaous formulations have been updated to include BUD of 14 days when refrigerated.	11/12/2025	N	
Clarification or Further Explanation	71	44.4	All aquaous formulations have been updated to include BUD of 14 days when refrigerated.	11/12/2025	N	
Clarification or Further Explanation	72	44.5	All aquaous formulations have been updated to include BUD of 14 days when refrigerated.	11/12/2025	N	
Clarification or Further Explanation	72	44.6	All aquaous formulations have been updated to include BUD of 14 days when refrigerated.	11/12/2025	N	
Clarification or Further Explanation	72	44.7	All aquaous formulations have been updated to include BUD of 14 days when refrigerated.	11/12/2025	N	
Clarification or Further Explanation	79	58.0	Company policy requires cleaning sanitizing per USP <795> guidelines Table 1 as included in our company policy and procedure manual. All staff performing non-sterile compounding to be retrained on this policy and requirements.	12/1/2025	N	
Clarification or Further Explanation	82	58.18	Company policy requires cleaning sanitizing per USP <795> guidelines Table 1 as included in our company policy and procedure manual. All staff performing non-sterile compounding to be retrained on this policy and requirements.	12/1/2025	N	
Clarification or Further Explanation	84	61.0	Company policy requires cleaning sanitizing per USP <795> guidelines Table 1 as included in our company policy and procedure manual. All staff performing non-sterile compounding to be retrained on this policy and requirements.	12/1/2025	N	
Clarification or Further Explanation	84	61.1	Company policy requires cleaning sanitizing per USP <795> guidelines Table 1 as included in our company policy and procedure manual. All staff performing non-sterile compounding to be retrained on this policy and requirements.	12/1/2025	N	
			Company policy requires cleaning sanitizing per USP <795> guidelines Table 1 as included in our company policy and procedure manual. All staff			

This VPP Inspection response and documentation has been provided directly by the phar response to its VPP Inspection. The content of this response has not been verified or modified at this point in time, except to check for completeness of any attachments provided.

Pharmacy Name:	Amber Enterprises, Inc dba Amber Specialty Pharmacy
Pharmacy Address:	10004 S 152nd St, Suite A, Omaha, NE 68138
NABP Business e-Profile ID:	787800
VPP Inspection Date(s):	10/14/2025
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	84	61.3	Company policy requires cleaning sanitizing per USP <795> guidelines Table 1 as included in our company policy and procedure manual. All staff performing non-sterile compounding to be retrained on this policy and requirements.	12/1/2025	N	
Clarification or Further Explanation	84	61.4	Company policy requires cleaning sanitizing per USP <795> guidelines Table 1 as included in our company policy and procedure manual. All staff performing non-sterile compounding to be retrained on this policy and requirements.	12/1/2025	N	

This VPP Inspection response and documentation has been provided directly by the phar response to its VPP Inspection. The content of this response has not been verified or modified at this point in time, except to check for completeness of any attachments provided.

4PP

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 03611	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Specialty Pharmacy	☐ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: [redacted] ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: HYVACS, LLC d/b/a Hy-Vee Pharmacy Solutions

Physical Address: 10004 S. 152nd St., Suite C

City: Omaha State: NE Zip: 68138

Mailing Address (if different from physical address): [Same as physical address]

City: _____ State: _____ Zip: _____

Telephone: 402-861-4938 Toll Free # (NAC 639.708, NRS 639.23286): 877-794-9833

Fax: 402-861-4941 Contact Email: licensure@hvrxsolutions.com

Website: www.hvrxsolutions.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Rusty Helser

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21224

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Rusty Helser	NV Pharmacist Registration #: 21224
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Iowa

Parent Company (if any): CenterWell Pharmacy, Inc.

Corporation/Organization Name: HYVACS, LLC d/b/a Hy-Vee Pharmacy Solutions

Mailing Address: 10004 S. 152nd St., Suite C

City: Omaha State: NE Zip: 68138

Telephone: 402-861-4938 Email: licensure@hvrxsolutions.com

Contact Person Name: Tanisha Curtis

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for HYVACS, LLC d/b/a Hy-Vee Pharmacy Solutions (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Bethanie Stein

Print Name of Authorized Person

Bethanie J Stein

Original signature of Authorized Person (copies or stamps not accepted)

7-13-26

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Bethanie Stein hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for HYVACS, LLC d/b/a Hy-Vee Pharmacy Solutions (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Bethanie J Stein

Original signature of Authorized Person (copies or stamps not accepted)

SUBSCRIBED AND SWORN TO
Before me, a notary public this 13th day of July, 2026

Caitlin Vanover

Notary Public

Caitlin Rae Vanover
Notary Public, ID KYNP70542
State at Large, Kentucky
My Commission Expires on April 13, 2027

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Bethanie Stein

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Bethanie Stein — 7-13-26

Original signature of Authorized Person (copies or stamps not accepted) — Date

Board Use Only	Date Received: 7/21/26	Amount: $500-2496095

HYVACS, LLC dba Hy-Vee Pharmacy Solutions

Disciplinary Actions

Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?

CenterWell Pharmacy, Inc. See attached Action Summary.

CenterWell Pharmacy

Summary of Actions

Maine Board of Pharmacy Complaint 2008-PHA-4787
In 2008, CenterWell Pharmacy, Inc. (formerly Humana Pharmacy, Inc.) located at 4302 W. Buckeye Rd., Phoenix, AZ 85043 admitted to a violation as a result of a complaint 2008-PHA-4787 where a prescription order was shipped to a patient who did not order the medication. There was no ingestion of the medication, and no patient harm. The root cause of the issue was Human Error. The Maine Board of Pharmacy offered a Consent Agreement where there was an admitted violation, a warning from the Board, and a $100 fine. This Agreement was previously reported to the Board.

Colorado Department of Commerce and Consumer Affair's Regulated Industries Complaints Office
CenterWell Pharmacy, Inc. (formerly Humana Pharmacy, Inc.) located at 4302 W. Buckeye Rd., Phoenix, AZ 85043 entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy on 5/19/2011. CenterWell Pharmacy, Inc. admitted to a violation of Board Rule 5.00.70 in which the pharmacy failed to timely submit the required applications and fees to the Colorado Board detailing a change in Pharmacist Managers. The violation was unintentional and root cause of the error was investigated and found to be an administrative error. The error was corrected, and imposed fees were paid. This Order was previously reported to the Board.

Hawaii Board of Pharmacy (PHA 2011-21-L and PHA 2010-32-L)
In December 2008, CenterWell Pharmacy, Inc. (formerly Humana Pharmacy, Inc.) located at 4302 W. Buckeye Rd., Phoenix, AZ 85043 entered into a Consent Agreement with the Maine Board of Pharmacy. Per Hawaii Revised Statutes, disciplinary decisions must be reported within 30 days. It is important to note that Humana Pharmacy, Inc. did notify the Hawaii Board of Pharmacy of the Consent Agreement. However, the notification exceeded the timeframe required by HRS 436B-19(15). PHA 2011-21-L is due to CenterWell Pharmacy, Inc. (formerly Humana Pharmacy, Inc.) receiving disciplinary action by another state agency. These agreements were previously reported to the Board.

Iowa Board of Pharmacy
CenterWell Pharmacy, Inc. (formerly Humana Pharmacy, Inc.) located at 4302 W. Buckeye Rd., Phoenix, AZ 85043 entered into a Settlement Agreement and Final Order with the Iowa Board of Pharmacy in August 2013. Pursuant to this Settlement Agreement and Final Order,

the Iowa Board of Pharmacy cited CenterWell Pharmacy, Inc. for having disciplinary action taken against it by another state licensing board. This action taken by the Iowa Board of Pharmacy is based entirely on the Settlement Agreement with the Hawaii Board of Pharmacy, and no new violations occurred. The Agreement was previously reported to the Board.

Michigan Board of Pharmacy
CenterWell Pharmacy, Inc. (formerly Humana Pharmacy, Inc.) located at 4302 W. Buckeye Rd., Phoenix, AZ 85043 entered into a Consent Order and Stipulation with the Michigan Department of Licensing and Regulatory Affairs which was received by CenterWell Pharmacy, Inc. in April 2014. The Administrative Complaint resulting in the Consent Order is in response to CenterWell Pharmacy, Inc. having violated section 17768(2) (d) of the Public Health Code due to receiving disciplinary action by other Regulatory Agencies. The Consent Order is based entirely on previously reported Settlement Agreements, and no new violations have occurred. The Order was previously reported to the Board.

Alaska Board of Pharmacy
CenterWell Pharmacy, Inc. (formerly Humana Pharmacy, Inc.) located at 4302 W. Buckeye Rd., Phoenix, AZ 85043 accepted an Imposition of Civil Fine without reprimand from the Alaska Board of Pharmacy in August 2014 due to a misinterpretation of a question on a 2010 renewal application. CenterWell Pharmacy, Inc. did not intentionally answer the question incorrectly, and it was answered based off of the interpretation of the question at that time. The action was previously reported to the Board.

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
HUMANA PHARMACY, INC.	)	CONSENT AGREEMENT
	)	
Complaint No. 2008-PHA-4787	)	

PARTIES

This document is a Consent Agreement regarding disciplinary action against Humana Pharmacy Inc.'s license to operate a mail order prescription pharmacy dispensing prescription drugs to patients residing in the State of Maine. The parties to this Consent Agreement are: Humana Pharmacy, Inc. ("Humana") with a principal place of business in Phoenix, Arizona, the State of Maine Board of Pharmacy ("the Board") and the Maine Office of the Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

FACTS

1. At all times pertinent to this matter, Humana was licensed by the Board to operate a mail order prescription pharmacy in Phoenix, Arizona dispensing prescription drugs to patients residing in Maine, license number MO40000472.
2. On or about July 10, 2008, the Board received a complaint against Humana pertaining to an alleged prescription order that was improperly sent to a consumer in Maine.
3. The Board docketed the complaint as Complaint No. 2008-PHA-4787.
4. The complaint alleges that on or about June 26, 2008, Humana sent a consumer residing in Maine prescription drugs that the consumer did not order.

5. The drug container was labeled by Humana with the name of the Maine resident and indicated that the prescribing practitioner was a physician from Florida.
6. Humana charged the cost of the drugs to the credit card of the Maine consumer and to Medicare.
7. On November 18, 2008, following a presentation of the complaint, the Board voted to offer Humana this Consent Agreement, in order to resolve Complaint No. 2008-PHA-4787. Absent acceptance of this Consent Agreement by signing and dating it and returning it to Kelly McLaughlin, Board Clerk, Board of Pharmacy, 35 State House Station, Augusta, Maine 04333-0035 by January 5, 2009, the Board will resolve this matter by holding an adjudicatory hearing.

COVENANTS

8. Humana admits that it was responsible for dispensing the erroneously filled prescription as described in paragraphs 4 through 6 above and admits that such conduct constitutes grounds for disciplining it pursuant to 10 M.R.S. § 8003(5-A)(A)(5), for violating a rule of the Board as follows:
    a. Chapter 30 § 15 by failing to establish and maintain effective controls to prevent prescription errors or misfills; and
    b. Chapter 30 § 16 by failing to address or attempt to resolve a possible prescription error which was apparent or should have been apparent.

9. As DISCIPLINE for the conduct admitted in paragraph 8 above, Humana agrees to

   a. Accept a WARNING; and

   b. Pay a CIVIL PENALTY in the amount of one hundred dollars ($100.00), which shall be made by check or money order payable to the "Treasurer, State of Maine" and delivered to Kelly McLaughlin, Board Clerk, Board of Pharmacy, 35 State House Station, Augusta, Maine 04333-0035, within thirty (30) days of the execution of this Consent Agreement.

10. Violation of any of the terms or conditions of this Consent Agreement by Humana shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

11. This Consent Agreement is not appealable and is effective until modified or rescinded by the parties hereto.

12. The Board and the Office of the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

13. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408.

14. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

15. Humana acknowledges by signature of an authorized representative hereto that it has read this Consent Agreement, that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executed this Consent Agreement of its own free will, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 12/18/08

For HUMANA PHARMACY, INC.

Dennis K. McAllister, Pharmacist in charge
Print Name and Title

DATED: 12/31/08

LORI A. McKEOWN, R.Ph., President
Maine Board of Pharmacy

DATED: 12/29/2008

ANDREW L. BLACK
Assistant Attorney General

BEFORE THE STATE BOARD OF PHARMACY
STATE OF COLORADO

Case Nos. 2011-1151 and 2011-1153

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION OF **HUMANA PHARMACY, INC.**, REGISTRATION NO. OSP 5672,

Respondent Pharmacy.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Humana Pharmacy, Inc. ("Respondent Pharmacy") to resolve all matters pertaining to Board Case Numbers 2011-1151 and 2011-1153, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Pharmacy, its registration as a non-resident prescription drug outlet, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S. (2010).

2. Respondent Pharmacy was originally registered as an non-resident prescription drug outlet in the State of Colorado on November 7, 2006, being issued registration number OSP 5672, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Pharmacy admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

4. Respondent Pharmacy's address of record with the Board and current location is 4302 West Buckeye Road, Phoenix, Arizona 85043.

5. On two separate occasions, Respondent Pharmacy failed to timely submit the required applications and fees to the Board detailing changes in pharmacist managers. In Board Case No. 2011-1151, a new pharmacist manager sent a letter to the Board on June 2, 2008 informing it that he had taken over as the new pharmacist manager, and asking if there was "anying further" required of him. However, the required application and fee were never submitted detailing him as the pharmacist manager during the 562-day time period that pharmacist served as manager between May 12, 2008 and February 1, 2010. In Board Case No. 2011-1153, 198 days elapsed during which time he served as interim pharmacist manager between February 1, 2010 and August 19, 2010 when the application and fee were received detailing him as the new pharmacist manager.

6. Respondent Pharmacy's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drugs.

12-22-130. Nonresident prescription drug outlet - registration.

(4) (a) The board may deny, revoke, or suspend a nonresident prescription drug outlet registration for failure to comply with any provision of this section or with any reasonable rule promulgated by the board.

* * *

Pharmacy Board Rules

5.00.70 Change in Pharmacist Manager.

b. The registration of any in-state and non-resident prescription drug outlet shall become void if the pharmacist manager in whose name the registration was issued ceases to be engaged as the manager, and the owner shall close the outlet unless such owner has employed a pharmacist manager and, within fourteen days after termination of the former manager's employment, has made application to transfer the registration to the new pharmacist manager and has paid the transfer fee therefor.

* * *

7. The Board finds and concludes, and Respondent Pharmacy agrees, that based upon Respondent Pharmacy's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

TERMS OF DISCIPLINE

8. **Fine with Surcharge.** Pursuant to §12-22-125.2(5), C.R.S., Respondent Pharmacy shall pay a fine of Five Thousand Dollars and No Cents ($5,000.00). Respondent Pharmacy understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 10% of this fine. Respondent Pharmacy shall therefore pay a total amount of Five Thousand Five Hundred Dollars and No Cents ($5,500.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Pharmacy submits this signed Final Agency Order to the Board.

9. **Compliance.** Respondent Pharmacy shall submit all future applications, on the form prescribed by the Board, to the Board detailing changes in pharmacist manager and fees within fourteen (14) days of the previous pharmacist manager ceasing the position.

10. **Other Requirements.** Respondent Pharmacy acknowledges and agrees that, as a condition of this Final Agency Order and probation, it shall:

    a. promptly pay all its own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. **Advisements and Waivers.** Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, after having consulted with legal counsel. Respondent Pharmacy acknowledges its understanding that it has the following rights:

    a. to have formal notice of hearing and charges served upon it;

    b. to respond to said formal notice of charges;

    c. to have a formal disciplinary hearing pursuant to Sections 12-22-125 and 12-22-125.2(2)(a), C.R.S.; and

    d. to appeal this Final Agency Order.

    Respondent Pharmacy freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Pharmacy to the sanctions imposed herein.

12. **Acknowledgments.** Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, after having consulted with legal counsel, that Respondent Pharmacy

understands its legal consequences and agrees that none of its terms or conditions is unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.

13. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Pharmacy's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.

14. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

15. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

Effective Date. This Final Agency Order shall become effective upon signature by a Board representative.

ACCEPTED AND AGREED BY

Respondent Pharmacy

William Fleming / VP
Authorized Representative / Title

Dated: 5/9/11

Subscribed and sworn to before me in the County of Jefferson, State of Kentucky, this 9 day of May, 2011 by William Fleming thorized representative of Humana Pharmacy, Inc.

My commission expires: 2/8/2015

Carol Keinsley
Notary Public

CAROL KEINSLEY
Notary Public
State at Large
Kentucky
My Commission Expires Feb 8, 2015

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 19th day of May, 2011.

State Board of Pharmacy

BY: Wendy Anderson
Wendy Anderson
Program Director

DOCUMENT APPROVED AS TO FORM

QUARLES & BRADY LLP

CHRISTINE CASSETTA*

Attorneys for Respondent Pharmacy

One Renaissance Square
Phoenix, Arizona 85004-2391
Telephone: (602) 229-5258
FAX: (602) 420-5036
christine.cassetta@quarles.com
*Counsel of Record

JOHN W. SUTHERS
Attorney General

JOANNA LEE KAYE, #20486*
Assistant Attorney General
Business and Licensing Section

Attorneys for State Board of Pharmacy

1525 Sherman Street, 5th Floor
Denver, Colorado 80203
Telephone: (303) 866-6170
FAX: (303) 866-5395
jo.kaye@state.co.us
*Counsel of Record

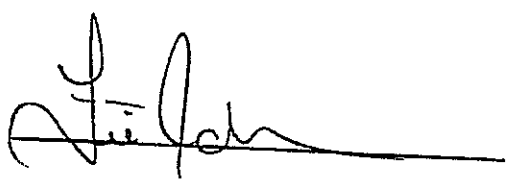
CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 19th day of May 2011, addressed as follows:

Christine Cassetta, Esq.
Quarles & Brady LLP
One Renaissance Square
Phoenix, Arizona 85004-2391

and via interagency mail to:

Jo Kaye
Assistant Attorney General



RECEIVED
PROFESSIONAL
2012 OCT 11 P 1:37
DEPT OF COMMERCE
AND CONSUMER AFFAIRS
STATE OF HAWAII

DENISE P. BALANAY 5526
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorney for Department of Commerce
and Consumer Affairs

RECEIVED
PROFESSIONAL
2012 DEC 20 P 1:19
DEPT OF COMMERCE
AND CONSUMER AFFAIRS
STATE OF HAWAII

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of HUMANA PHARMACY, INC., doing business as RIGHTSOURCE, Respondent.	PHA 2010-32-L SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"

248040108

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorneys, and Respondent HUMANA PHARMACY, INC., doing business as RIGHTSOURCE (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was permitted by the Board of Pharmacy (hereinafter the "Board") as a pharmacy under Miscellaneous Permit Number PMP 473. The

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

permit was issued on or about June 13, 2006. The permit will forfeit or expire on or about December 31, 2013.

2. Respondent's mailing address for purposes of this action is 4302 W. Buckeye Road, Phoenix, Arizona 85043.

3. RICO received information that, on or about December 18, 2008, Respondent entered into a Consent Agreement with the Maine Board of Pharmacy in In Re: Humana Pharmacy, Inc./Complaint No. 2008-PHA-4787 ("Maine Agreement"). A true and correct copy of the Maine Agreement is attached hereto as Exhibit "1."

4. RICO alleges although Respondent disclosed the Maine Agreement on a Renewal Application dated December 7, 2009, Respondent failed to report the Maine Agreement to the Board within thirty days of its issuance.

5. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(15) (failure to report disciplinary decision within thirty days) and § 436B-19(17) (violating applicable licensing laws).

6. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein permitted as a pharmacy by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's permit.

6. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

7. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2010-32-L.

8. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

C. TERMS OF SETTLEMENT:

1. Administrative Fine. Respondent agrees to pay a fine in the amount of ONE THOUSAND AND NO/100 DOLLARS ($1,000.00). Payment shall be made by cashier's check or money order made payable to "DCCA - Compliance Resolution Fund" and mailed to the Regulated Industries Complaints Office, Attn: Denise P. Balanay, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this fully executed Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1 above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the permit to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible Further Sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of pharmacies in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5, C.6, C.7 and C.8 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain will raise as an objection in

any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: Louisville (CITY), Kentucky (STATE). 10-8-2012 (DATE).

HUMANA PHARMACY, INC.

By: _____

Its PRESIDENT HPD

OCT 1 1 2012

DATED: Honolulu, Hawaii, _____.

_____

DENISE P. BALANAY
Attorney for Department of Commerce
and Consumer Affairs

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

11-15-2012
DATE

MARK E. BROWN
Chairperson

PATRICK ADAMS
Vice Chairperson

TODD INAFUKU

GARRETT A. LAU

CAROLYN S.Y. MA

JILL OLIVEIRA GRAY

LYDIA KUMASAKA

PVL 07/15/11

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
HUMANA PHARMACY, INC.	)	CONSENT AGREEMENT
	)	
Complaint No. 2008-PHA-4787	)	

PARTIES

This document is a Consent Agreement regarding disciplinary action against Humana Pharmacy Inc.'s license to operate a mail order prescription pharmacy dispensing prescription drugs to patients residing in the State of Maine. The parties to this Consent Agreement are: Humana Pharmacy, Inc. ("Humana") with a principal place of business in Phoenix, Arizona, the State of Maine Board of Pharmacy ("the Board") and the Maine Office of the Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

FACTS

1. At all times pertinent to this matter, Humana was licensed by the Board to operate a mail order prescription pharmacy in Phoenix, Arizona dispensing prescription drugs to patients residing in Maine, license number MO40000472.
2. On or about July 10, 2008, the Board received a complaint against Humana pertaining to an alleged prescription order that was improperly sent to a consumer in Maine.
3. The Board docketed the complaint as Complaint No. 2008-PHA-4787.
4. The complaint alleges that on or about June 26, 2008, Humana sent a consumer residing in Maine prescription drugs that the consumer did not order.

EXHIBIT 1

5. The drug container was labeled by Humana with the name of the Maine resident and indicated that the prescribing practitioner was a physician from Florida.
6. Humana charged the cost of the drugs to the credit card of the Maine consumer and to Medicare.
7. On November 18, 2008, following a presentation of the complaint, the Board voted to offer Humana this Consent Agreement, in order to resolve Complaint No. 2008-PHA-4787. Absent acceptance of this Consent Agreement by signing and dating it and returning it to Kelly McLaughlin, Board Clerk, Board of Pharmacy, 35 State House Station, Augusta, Maine 04333-0035 by January 5, 2009, the Board will resolve this matter by holding an adjudicatory hearing.

COVENANTS

8. Humana admits that it was responsible for dispensing the erroneously filled prescription as described in paragraphs 4 through 6 above and admits that such conduct constitutes grounds for disciplining it pursuant to 10 M.R.S. § 8003(5-A)(A)(5), for violating a rule of the Board as follows:
    a. Chapter 30 § 15 by failing to establish and maintain effective controls to prevent prescription errors or misfills; and
    b. Chapter 30 § 16 by failing to address or attempt to resolve a possible prescription error which was apparent or should have been apparent.

9. As DISCIPLINE for the conduct admitted in paragraph 8 above, Humana agrees to

   a. Accept a WARNING; and

   b. Pay a CIVIL PENALTY in the amount of one hundred dollars ($100.00), which shall be made by check or money order payable to the "Treasurer, State of Maine" and delivered to Kelly McLaughlin, Board Clerk, Board of Pharmacy, 35 State House Station, Augusta, Maine 04333-0035, within thirty (30) days of the execution of this Consent Agreement.

10. Violation of any of the terms or conditions of this Consent Agreement by Humana shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

11. This Consent Agreement is not appealable and is effective until modified or rescinded by the parties hereto.

12. The Board and the Office of the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

13. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408.

14. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

15. Humana acknowledges by signature of an authorized representative hereto that it has read this Consent Agreement, that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executed this Consent Agreement of its own free will, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 12/18/08

For HUMANA PHARMACY, INC.

Print Name and Title

DATED: 12/31/08

LORI A. McKEOWN, R.Ph., President
Maine Board of Pharmacy

DATED: 12/24/2008

ANDREW L. BLACK
Assistant Attorney General

DEPT OF COMMERCE
AND CONSUMER AFFAIRS
2012 DEC 20 P 1:18
RECEIVED

DENISE P. BALANAY 5526
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorney for Department of Commerce
and Consumer Affairs

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of HUMANA PHARMACY, INC., doing business as RIGHTSOURCE, Respondent.	PHA 2011-21-L SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; EXHIBIT "1"

248040108

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS' REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"), through its undersigned attorneys, and Respondent HUMANA PHARMACY, INC., doing business as RIGHTSOURCE (hereinafter "Respondent"), enter into this Settlement Agreement on the terms and conditions set forth below.

A. UNCONTESTED FACTS:

1. At all relevant times herein, Respondent was permitted by the Board of Pharmacy (hereinafter the "Board") as a pharmacy under Miscellaneous Permit Number PMP 473.

I HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE ORIGINAL ON FILE IN THE DEPARTMENT OF COMMERCE & CONSUMER AFFAIRS.

The permit was issued on or about June 13, 2006. The permit will forfeit or expire on or about December 31, 2013.

2. Respondent's mailing address for purposes of this action is 4302 W. Buckeye Road, Phoenix, Arizona 85043.

3. RICO received information that, on or about May 9, 2011, Respondent entered into a Stipulation and Final Agency Order with the State Board of Pharmacy for the State of Colorado ("Stipulation"). A true and correct copy of the Stipulation is attached as Exhibit "1."

4. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s): Hawaii Revised Statutes ("HRS") § 436B-19(13) (disciplinary action by another state or federal agency for any reason provided by licensing laws) and § 436B-19(17) (violating applicable licensing laws).

5. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein permitted as a pharmacy by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of the permit and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's permit.

6. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

7. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2011-21-L.

8. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

C. TERMS OF SETTLEMENT:

1. Administrative Fine. Respondent agrees to pay a fine in the amount of FIVE HUNDRED AND NO/100 DOLLARS ($500.00). Payment shall be made by cashier's check or money order made payable to "DCCA - Compliance Resolution Fund" and mailed to the Regulated Industries Complaints Office, Attn: Denise P. Balanay, Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this fully executed Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1 above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all

indicia of the permit to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible Further Sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of pharmacies in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

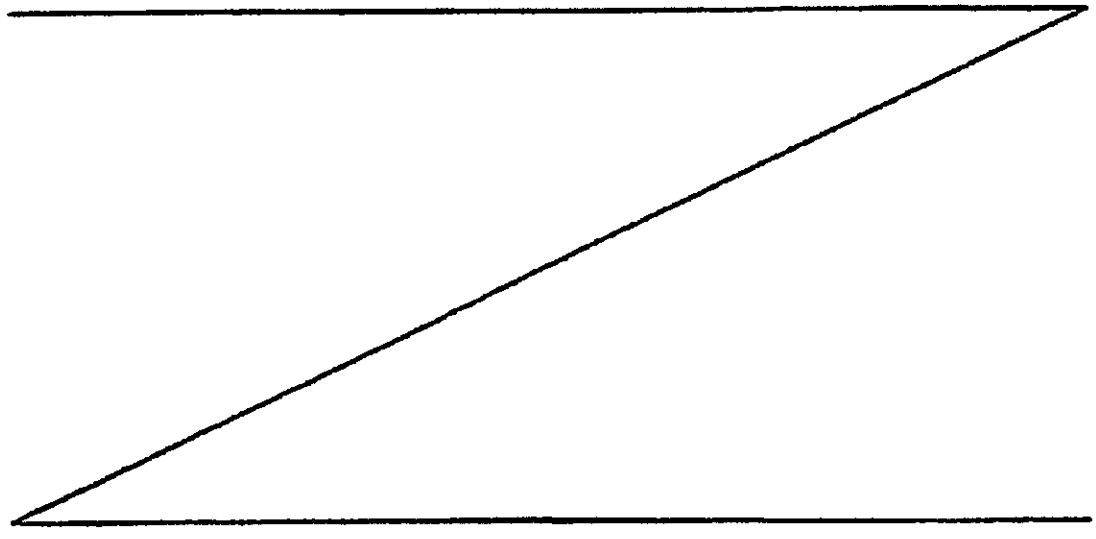
4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5, C.6, C.7 and C.8 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.



IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: Louisville (CITY), Kentucky (STATE), 10·8·2012 (DATE).

HUMANA PHARMACY, INC.

By: _____

Its _____

DATED: Honolulu, Hawaii, OCT 11 2012.

DENISE P. BALANAY
Attorney for Department of Commerce
and Consumer Affairs

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF HUMANA PHARMACY, INC., DOING BUSINESS AS RIGHTSOURCE; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER; CASE NO. PHA 2011-21-L; EXHIBIT "1"

APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII

MARK E. BROWN
Chairperson

11/15/2012
DATE

PATRICK ADAMS
Vice Chairperson

TODD INAFUKU

GARRETT A. LAU

CAROLYN S. Y. MA

JILL OLIVEIRA GRAY

LYDIA KUMASAKA

PVL 07/15/11

BEFORE THE STATE BOARD OF PHARMACY
STATE OF COLORADO

Case Nos. 2011-1151 and 2011-1153

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION OF HUMANA PHARMACY, INC., REGISTRATION NO. OSP 5672,

Respondent Pharmacy.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Humana Pharmacy, Inc. ("Respondent Pharmacy") to resolve all matters pertaining to Board Case Numbers 2011-1151 and 2011-1153, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Pharmacy, its registration as a non-resident prescription drug outlet, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S. (2010).

2. Respondent Pharmacy was originally registered as an non-resident prescription drug outlet in the State of Colorado on November 7, 2006, being issued registration number OSP 5672, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Pharmacy admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

4. Respondent Pharmacy's address of record with the Board and current location is 4302 West Buckeye Road, Phoenix, Arizona 85043.

5. On two separate occasions, Respondent Pharmacy failed to timely submit the required applications and fees to the Board detailing changes in pharmacist managers. In Board Case No. 2011-1151, a new pharmacist manager sent a letter to the Board on June 2, 2008 informing it that he had taken over as the new pharmacist manager, and asking if there was "anying further" required of him. However, the required application and fee were never submitted detailing him as the pharmacist manager during the 562-day time period that pharmacist served as manager between May 12, 2008 and February 1, 2010. In Board Case No. 2011-1153, 198 days elapsed during which time he served as the pharmacist manager between February 1, 2010 and August 19, 2010 when the application and fee were received detailing him as the new pharmacist manager.

RECEIVED
PROF & VOCATIONAL LICENSING SVCS
2011 MAR -3 A 11
DEPT OF REGULATORY AGENCIES
CONSUMER AFFAIRS
STATE OF HAWAII

EXHIBIT 7

6. Respondent Pharmacy's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drugs.

12-22-130. Nonresident prescription drug outlet - registration.

(4) (a) The board may deny, revoke, or suspend a nonresident prescription drug outlet registration for failure to comply with any provision of this section or with any reasonable rule promulgated by the board.

* * *

Pharmacy Board Rules

5.00.70 Change in Pharmacist Manager.

b. The registration of any in-state and non-resident prescription drug outlet shall become void if the pharmacist manager in whose name the registration was issued ceases to be engaged as the manager, and the owner shall close the outlet unless such owner has employed a pharmacist manager and, within fourteen days after termination of the former manager's employment, has made application to transfer the registration to the new pharmacist manager and has paid the transfer fee therefor.

* * *

7. The Board finds and concludes, and Respondent Pharmacy agrees, that based upon Respondent Pharmacy's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

RECEIVED
PROF & VOCATIONAL
LICENSING DIVISION
'91 JUN -3 A 11:40
DEPT OF COMMERCE
CONSUMER AFFAIRS
STATE OF HAWAII

TERMS OF DISCIPLINE

8. Fine with Surcharge. Pursuant to §12-22-125.2(5), C.R.S., Respondent Pharmacy shall pay a fine of Five Thousand Dollars and No Cents ($5,000.00). Respondent Pharmacy understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 10% of this fine. Respondent Pharmacy shall therefore pay a total amount of Five Thousand Five Hundred Dollars and No Cents ($5,500.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Pharmacy submits this signed Final Agency Order to the Board.

9. Compliance. Respondent Pharmacy shall submit all future applications, on the form prescribed by the Board, to the Board detailing changes in pharmacist manager and fees within fourteen (14) days of the previous pharmacist manager ceasing the position.

10. Other Requirements. Respondent Pharmacy acknowledges and agrees that, as a condition of this Final Agency Order and probation, it shall:

    a. promptly pay all its own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. Advisements and Waivers. Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, after having consulted with legal counsel. Respondent Pharmacy acknowledges its understanding that it has the following rights:

    a. to have formal notice of hearing and charges served upon it;

    b. to respond to said formal notice of charges;

    c. to have a formal disciplinary hearing pursuant to Sections 12-22-125 and 12-22-125.2(2)(a), C.R.S.; and

    d. to appeal this Final Agency Order.

    Respondent Pharmacy freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Pharmacy to the sanctions imposed herein.

12. Acknowledgments. Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, after having consulted with legal counsel, that Respondent Pharmacy

RECEIVED
PROF & VOCATIONAL
LICENSING DIVISION
2008 JUL -3 A 11: 49
DEPT OF COMMERCE
& CONSUMER AFFAIRS
STATE OF HAWAII

understands its legal consequences and agrees that none of its terms or conditions is unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.

13. Violations. Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Pharmacy's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.

14. Integration and Severability. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

15. Public Record. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

Effective Date. This Final Agency Order shall become effective upon signature by a Board representative.

ACCEPTED AND AGREED BY

Respondent Pharmacy

Jeff Kelly / VP
Authorized Representative/Title

Dated: 5/9/11

Subscribed and sworn to before me in the County of Jefferson,
State of Kentucky, this 9 day of May, 2011 by
William Fleming thorized representative of Humana Pharmacy, Inc.

My commission expires: 2/8/15

Notary Public

CAROL KENDLEY
Notary Public
State at Large
Kentucky
My Commission Expires Feb 8, 2015

RECEIVED
PROFESSIONAL & OCCUPATIONAL LICENSING DIVISION
2011 JUN -6 A 11:49
DEPT OF COMMERCE & CONSUMER AFFAIRS
STATE OF HAWAII

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 19th day of May, 2011.

State Board of Pharmacy

BY: _____
Wendy Anderson
Program Director

DOCUMENT APPROVED AS TO FORM

QUARLES & BRADY LLP

_____
CHRISTINE CASSETTA*

Attorneys for Respondent Pharmacy

One Renaissance Square
Phoenix, Arizona 85004-2391
Telephone: (602) 229-5258
FAX: (602) 420-5036
christine.cassetta@quarles.com
*Counsel of Record

JOHN W. SUTHERS
Attorney General

_____
JOANNA LEE KAYE, #20436*
Assistant Attorney General
Business and Licensing Section

Attorneys for State Board of Pharmacy

1525 Sherman Street, 5th Floor
Denver, Colorado 80203
Telephone: (303) 866-6170
FAX: (303) 866-5395
jo.kaye@state.co.us
*Counsel of Record

RECEIVED
PROF & VOCATIONAL
LICENSING DIVISION
2011 JUN -3 A 11:09
DEPT OF COMMERCE
& CONSUMER AFFAIRS
STATE OF HAWAII

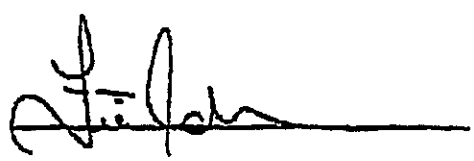
CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 19th day of May 2011, addressed as follows:

Christine Cassetta, Esq.
Quarles & Brady LLP
One Renaissance Square
Phoenix, Arizona 85004-2391

and via interagency mail to:

Jo Kaya
Assistant Attorney General



RECEIVED
PROF & VOCATIONAL
LICENSING DIVISION
2011 JUN -3 A 11:49
DEPT OF COMMERCE
& CONSUMER AFFAIRS
STATE OF HAWAII

BEFORE THE IOWA BOARD OF PHARMACY

Re: Nonresident Pharmacy License of **RIGHTSOURCE** License No. 3659 Respondent.	)))))))	Case No. 2012-14 **SETTLEMENT AGREEMENT AND FINAL ORDER**

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2013), the Iowa Board of Pharmacy and RightSource, Respondent, enter into this Settlement Agreement and Final Order to settle the licensee disciplinary proceeding currently pending before the Board.

The allegations contained in a Statement of Charges against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. Respondent was issued Nonresident Pharmacy License No. 3659. That license is active and will expire on December 31, 2013.
2. A Statement of Charges was filed against Respondent on April 23, 2013. Subsequent to April 23, 2013, the parties entered into ongoing discussions regarding the allegations set forth in the Statement of Charges.
3. At all times relevant to the Statement of Charges, Respondent operated a nonresident pharmacy in Phoenix, Arizona.

RECEIVED
AUG 22 2013
IOWA BOARD OF PHARMACY

4. The Board has jurisdiction over the parties and the subject matter of these proceedings.

5. Respondent has chosen not to contest the allegations in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline agreed to in this Order.

6. Respondent is hereby CITED for having disciplinary action taken against it by another state licensing board, and is hereby WARNED that future violations of the law governing the practice of pharmacy in Iowa could result in further disciplinary action.

7. Respondent agrees to pay a civil penalty in the amount of $1000. This civil penalty shall be made payable to the Treasurer of Iowa and mailed to the executive director of the Board within twenty (20) days of the Board's approval of this Settlement Agreement and Final Order. All civil penalty payments shall be deposited into the State of Iowa general fund.

8. This Settlement Agreement and Final Order is the resolution of a contested case. By entering into this Settlement Agreement and Final Order, Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges, and waives any objections to this Final Order.

9. The State's legal counsel may present this Settlement Agreement and Final Order to the Board.

10. This Settlement Agreement and Final Order is subject to approval by a majority of the full Board. If the Board fails to approve this settlement, it shall be

of no force or effect to either the Board or Respondent. If the Board approves this Settlement Agreement and Final Order, it shall be the full and final resolution of this matter.

11. The Board's approval of this Settlement Agreement and Final Order shall constitute a FINAL ORDER of the Board.

This Settlement Agreement and Final Order is voluntarily submitted by Respondent to the Board for its consideration on the 15 day of August, 2013.

For Respondent

By this signature, Scott Greenwell acknowledges s/he is authorized to sign this Settlement Agreement and Final Order on behalf of RightSource.

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy on the 28th day of August 2013.

EDWARD L. MAIER, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Theresa O=Connell Weeg
Assistant Attorney General
Office of the Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

RECEIVED
JAN 29 2014
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
LICENSING SECTION

In the Matter of

RIGHT SOURCE
a/k/a Humana Pharmacy, Inc.
License Number: 53-01-008370

File Number: 53-13-128340
CONSENT ORDER AND STIPULATION

CONSENT ORDER

WHEREAS, an Administrative Complaint, hereafter Complaint, was issued on August 8, 2013, charging Right Source, a/k/a Humana Pharmacy, Inc., hereafter Respondent Pharmacy, with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq; and

WHEREAS, Respondent Pharmacy neither admits nor denies the facts alleged in the Complaint dated August 8, 2013, but agrees that the Disciplinary Subcommittee of the Michigan Board of Pharmacy, hereafter Disciplinary Subcommittee, shall treat the allegations as true for the purposes of this Consent Order, which findings shall have the same force and effect as if evidence and argument were presented in support of the allegations; and

WHEREAS, the Disciplinary Subcommittee has reviewed the Stipulation and, based upon the matters asserted therein, agrees that the public interest is best served by resolution of the outstanding Complaint; now therefore,

IT IS HEREBY FOUND that the facts alleged in the Complaint are true, for the purposes of this Consent Order, and constitute a violation of section 17768(2)(d) of the Public Health Code, supra.

Accordingly,

IT IS HEREBY ORDERED that for the cited violation of the Public Health Code, Respondent Pharmacy is FINED in the amount of $1,500.00 to be paid to the State of Michigan within 60 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs, Enforcement Division, Sanction Monitoring, P.O. Box 30189, Lansing, MI 48909**. The fine shall be paid by check or money order, made payable to the State of Michigan, and the check or money order shall clearly display file number **53-13-128340**.

IT IS FURTHER ORDERED that in the event Respondent Pharmacy violates any provision of this Order, the Disciplinary Subcommittee may proceed to take disciplinary action pursuant to 1996 AACS, R 338.1632 and section 16221(h) of the Public Health Code, supra.

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

Dated: 9/9/14

MICHIGAN BOARD OF PHARMACY

By: _____
Chairperson, Disciplinary Subcommittee

STIPULATION

1. Respondent Pharmacy neither admits nor denies the facts alleged in the Complaint dated August 8, 2013, but agrees that the Disciplinary Subcommittee shall treat the allegations as true for the purposes of this Consent Order, which findings shall have the same force and effect as if evidence and argument were presented in support thereof.

2. Respondent Pharmacy understands and intends that by signing this Stipulation Respondent Pharmacy is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq, to require the Department of Licensing and Regulatory Affairs, hereafter Department, to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent Pharmacy is waiving the right to appear with an attorney and such witnesses as Respondent Pharmacy may desire to present a defense to the charges.

3. Patricia Smeelink, R.Ph., a member of the Michigan Board of Pharmacy who supports this proposal, and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in the foregoing Consent Order.

4. The foregoing Consent Order is approved as to form and substance by Respondent Pharmacy and the Department and may be entered as the final order of the Disciplinary Subcommittee in this cause.

5. The foregoing proposal is conditioned upon acceptance by the Disciplinary Subcommittee, Respondent Pharmacy and the Department expressly reserving the right to further proceedings without prejudice should the Consent Order be rejected.

AGREED TO BY:

Carole H. Engle, Director
Bureau of Health Care Services
Department of Licensing and
Regulatory Affairs

Dated: 1-31-14

AGREED TO BY:

Michael Kuratko
Authorized Representative
for Respondent Pharmacy

Dated: 1/28/2014

This is the final page of a Consent Order and Stipulation in the matter of Right Source, a/k/a Humana Pharmacy Inc., File Number 53-12-128340, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of four pages, this page included.

AS

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE ALASKA BOARD OF PHARMACY

IMPOSITION OF CIVIL FINE
Case # 2014-000669

RightSource admits and agrees that the Alaska Board of Pharmacy (Board) has jurisdiction over the subject matter of their license in Alaska and over this Imposition of Civil Fine.

1. The Board alleges that RightSource during their Biennial license renewal periods from 2010-2012 and 2012-2014, failed to disclose information concerning prior licensing actions taken against one of their companies in 2008 which is in violation of 12 AAC 52.920 (a)(13) and 12 AAC 052.991.

2. RightSource admits this error was an oversight on their part and that they have taken steps to ensure this error does not occur again.

RightSource does not contest that the Board's allegations, which if proven could be grounds for possible denial of licensure or other disciplinary sanctions of their license pursuant to AS 08.80.030 (b)(5), AS 08.01.075, AS 08.80.261 and 12 AAC 52.920. In order to resolve this matter, RightSource is agreeing to this Imposition of a Civil Fine of one thousand dollars ($1000) in cash, certified check, or money order payable to the "State of Alaska" within ninety (90) days after this Imposition of Civil Fine is accepted by the Board

RightSource has the right to consult with an attorney and the right to have an administrative hearing on the facts in this case. RightSource understands and agrees that by voluntarily signing this Imposition of Civil Fine, they are waiving their rights to counsel and to a hearing on this matter.

On Behalf of RightSource

7/25/2014
Date

ORDER

The Alaska Board of Pharmacy hereby adopts the Imposition of Civil Fine in this matter. The Board has determined that this violation of professional licensing statutes and regulations can be resolved with a civil fine.

This Imposition of Civil Fine takes effect immediately upon signature of this Order in accordance with the approval of the Board.

DATED this 7th day of AUGUST, 2014, at ANCHORAGE, Alaska.

BOARD OF PHARMACY

By:
Dirk White-Chairperson

State of Alaska
Department of Commerce, Community, and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

Top 5 Officers

HYVACS, LLC dba Hy-Vee Pharmacy Solutions

Officers and Directors

Name	Title
Bethanie Lynn Stein	President
Sean Michael Lysinger	Vice President, Chief Financial Officer, Pharmacy
Robert Martin Marcoux, Jr.	Director, Vice President and Treasurer
Daniel Kevin Feld	Director & Associate Vice President, Tax
Valerie M. Talkers	Director, Vice President, Associate General Counsel and Corporate Secretary

The Pharmacy is wholly owned by
HYVACS, LLC dba Hy-Vee Pharmacy Solutions
FEIN: 27-1159217
10004 S 152nd St. Ste. C
Omaha, NE 68138

HYVACS, LLC dba Hy-Vee Pharmacy Solutions is wholly owned by
CenterWell Pharmacy, Inc.
FEIN: 61-1316926
101 East Main Street
Louisville, KY 40202

IOWA SECRETARY OF STATE
PAUL D. PATE

CERTIFICATE OF EXISTENCE

Issue Date: 5/14/2026

Name: HYVACS, LLC (489DLC - 384700)
Date of Formation: 10/21/2009
Duration: PERPETUAL

I, Paul D. Pate, Secretary of State of the State of Iowa, custodian of the records of incorporations, certify the following for the limited liability company named on this certificate:

a. The entity is in existence and duly formed under the laws of Iowa. A certificate of organization has been filed and has taken effect.

b. All fees, taxes and penalties required under the Revised Uniform Limited Liability Company Act and other laws due the Secretary of State have been paid.

c. The most recent biennial report required has been filed with the Secretary of State.

d. The Secretary of State has not administratively dissolved the limited liability company.

e. The Secretary of State has not filed either a statement of dissolution or statement of termination. The records of the Secretary of State do not otherwise reflect that the limited liability company has been dissolved or terminated.

f. A proceeding is not pending under section 489.705

Certificate ID: **CS324398**

To validate certificates visit:
sos.iowa.gov/ValidateCertificate

Paul D. Pate, Iowa Secretary of State

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler HYVACS, LLC d/b/a Hy-Vee Pharmacy Solutions

Pharmacy/Wholesaler License # (if applicable) PH03611

Physical Address 10004 S. 152nd St., Suite C

City Omaha State NE Zip 68138

Mailing Address (if different from physical address) [Same as physical address]

City _____ State _____ Zip _____

Telephone 402-861-4938 Website www.hvrxsolutions.com

Licensing Company Email licensure@hvrxsolutions.com

Section 2: Personal Information

First Rusty Middle Ryan Last Helser

Alias(es, nicknames, name changes, etc.) N/A

Date of Birt[redacted] SSN or ITIN[redacted] Sex ☒ M ☐ F ☐ X

Mailing Address[redacted]

City Gretna State NE Zip[redacted]

Telephone[redacted] Email[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: UNMC College of Pharmacy			From - To (MM/YY – MM/YY): 08/00-05/04
Address	City: Omaha	State: NE	Zip
Diploma/Degree obtained, if any: Doctor of Pharmacy			
School Name: Chadron State College			From - To (MM/YY – MM/YY): 08/97-05/00
Address	City: Chadron	State: NE	Zip
Diploma/Degree obtained, if any: Bachelor of Science Health Science			
School Name: Mitchell Jr/Sr High School			From - To (MM/YY – MM/YY): 08/93-05/97
Address	City: Mitchell	State: NE	Zip
Diploma/Degree obtained, if any: Diploma			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): 05/17-current	[redacted]	City: Gretna	State: NE	[redacted]
From - To (MM/YY – MM/YY): 10/05-04/17	[redacted]	City: Omaha	State: NE	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Amber Specialty Pharmacy			From - To (MM/YY – MM/YY): 11/2010-current	
Business Address: 10004 S 152nd St Ste. A	City: Omaha		State: NE	Zip: 68138
Phone:	Title: Pharmacist		Number of Employed Hours: 40 hrs weekly	
Description of Duties:				

Business Name: Hy-Vee Pharmacy Solutions			From - To (MM/YY – MM/YY): 11/2010-current	
Business Address: 10004 S 152nd St Ste. C	City:		State:	Zip:
Phone:	Title: Pharmacy Manager/PIC		Number of Employed Hours:	
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

7/9/2026
Date

I, Rusty Helser, **certify that as the designated representative for**

HYVACS, LLC d/b/a Hy-Vee Pharmacy Solutions,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RH I am at least 21 years of age;
3. RH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Rusty Helser

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/9/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rusty Helser

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/9/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Nebraska, ss. County of Sarpy

I, Rusty Helser, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/9/2026

Date

Subscribed and Sworn to before me this 9th day of July 2026

Notary Public Signature

GENERAL NOTARY-State of Nebraska
CATHY CATTLETT
My Comm. Exp. July 15, 2028

(Seal)

STATE OF NEBRASKA
DEPARTMENT OF HEALTH & HUMAN SERVICES
DIVISION OF PUBLIC HEALTH
Licensure Unit
P. O. Box 94986
Lincoln, NE 68509-4986

PHARMACY QUALITY ASSURANCE REPORT

Pharmacy License Number: #3010 Exp. Date: 7/1/26

DEA registration Number: FH4608723 Exp. Date: 10/31/28

Owner's Name: Hy-Vee, Inc

Pharmacy Name: HYVACS, LLC dba Hy-Vee Pharmacy Solutions

Pharmacy Street Address: 10004 S 152nd St Ste C

Pharmacy City, State, Zip Code Omaha, NE 68138

Pharmacy Telephone #: (877) 794-9833 Pharmacy Fax #: (402) 861-4941

Pharmacy E-mail: rhelser@amberpharmacy.com

Pharmacy Hours: Mon - Fri 8 am - 5 pm

List Pharmacy Personnel:

Name of Pharmacist-In-Charge: Rusty Helser RP License #12057

Staff Pharmacists & Interns Name & NE RPh. License # Or NE Intern Registration #	**Pharmacy Technicians Name & NE Registration #**	**Technician Certifying Body, Certification # if applicable, & Certification Expiration Date**
Pamela Helser #12525	Margaret Sargent #8263	NHA #W4T4T5X6 2/4/28
Brianda Fagundes #18374	Sydney Ash #11060	PTCB #30162625 4/30/27
Lori Wells #12881	Reeghan Kaminski #11380	NHA #G9D2Q6H7 2/14/28
Jennifer Howder #12756	Shannon Thomas #9398	PTCB #30091355 2/28/27
Amy Adams #12025	____ #____	____ #____ ____
Kelli Wyant #12505	____ #____	____ #____ ____
Connie Kerkove #13467	____ #____	____ #____ ____
Jill Allard #12043	____ #____	____ #____ ____
Samiullah Amini #15394	____ #____	____ #____ ____
Amy Barry #12303	____ #____	____ #____ ____
____ #____	____ #____	____ #____ ____
____ #____	____ #____	____ #____ ____

SOFTWARE: Care Tend RX'S PER DAY: 20-25

Melissa Pollard
(Pharmacy Inspector)

4/28/26
(Date of Inspection)

Section Cited	Requirement	C	NC	NA
CFR = 21 CFR Ch.II NAC = Nebraska Administrative Code NRS = Nebraska Revised Statute USC = United States Code USP= United States Pharmacopeia	C = In Compliance NC = Not in Compliance NA = Not Applicable	C	NC	NA
175 NAC 8-005	1. All information provided on the current pharmacy license document is correct.	☒	☐	☐
172 NAC 128-006	2. Each Pharmacist, Pharmacist Intern and Pharmacy Technician are identified as such.	☒	☐	☐
175 NAC 8-006.01A	3. Pharmacy employs a sufficient number of licensed pharmacists to safely meet the needs of individuals seeking services at the pharmacy.	☒	☐	☐
175 NAC 8-007.01 NRS 28-410, CFR 1301.71	4. Adequate security is maintained for the prescription inventory and prescription records.	☒	☐	☐
175 NAC 8-006.02	5. Drugs, devices, and biologicals are stored under proper conditions.	☒	☐	☐
175 NAC 8-008.02 NRS 38-2866	6. The pharmacy is: • maintained in a clean, orderly, and sanitary manner; • open for the practice of pharmacy only when a pharmacist is physically present.	☒ ☒	☐ ☐	☐ ☐
175 NAC 8-008.03	7. The pharmacy maintains in printed or electronic form appropriate reference material for the practice of pharmacy.	☒	☐	☐
175 NAC 8-008.01 NRS 38-2867.01 USP 795 USP 797	8. The pharmacy provides access to all utilities/equipment needed to practice pharmacy. Water used for compounding is at USP standards. When applicable, water purification systems are maintained.	☒	☐	☐
NRS 38-2869 (2)(a)	9. Patient counseling is being provided as required.	☒	☐	☐
NRS 38-2869 (2)(a)	10. The pharmacy maintains documentation of a patient's refusal of counseling.	☒	☐	☐
NRS 38-2830	11. Patient counseling is being done by only a pharmacist or pharmacist intern.	☒	☐	☐
NRS 38-2869(1)	12. Prior to the dispensing or the delivery of each new or refill prescription, a pharmacist is conducting a prospective drug utilization review.	☒	☐	☐
NRS 28-414.02 CFR 1304, 1306 CFR 1311	13. All computer or electronic record keeping requirements are met including requirements for electronic prescriptions for controlled substances.	☒	☐	☐
CFR 1305 CFR 1311	14. Acquisition and distribution requirements for Schedule II controlled substances are met regarding the use of an official order form or the electronic equivalent. Power of Attorney forms completed and filed when applicable.	☐	☐	☒

Section Cited	Requirement	C	NC	NA
NRS 28-411 CFR 1304	15. The pharmacy maintains complete and accurate records of all controlled substances received and/or distributed.	☒	☐	☐
NRS 28-414.05 CFR 1304.22 CFR 1317	16. The pharmacy complies with all transfer and/or destruction requirements for controlled substances.	☒	☐	☐
21 U.S. Code 351 21 U.S. Code 352 NRS 71-2461 NRS 71-2470	17. The pharmacy does not have in its saleable inventory any drug, device or biological which is misbranded or adulterated, as defined in statute.	☒	☐	☐
NRS 71-2479 NRS 38-28,107	18. The pharmacy assures that all requirements pertaining to unit dose packaging and returned product labeling are met.	☐	☐	☒
NRS 71-2479	19. The pharmacy assures that all requirements pertaining to multi-drug containers are met, including proper labeling.	☐	☐	☒
NRS 28-410 CFR 1304.11	20. All requirements pertaining to the inventory of controlled substances are met. The inventory is available at the registered location in **written, typewritten, or printed** form and contains the following: • **Date** the inventory was taken • Indicates **open or close** of business and the **time** of day the inventory was taken • **Schedule II** inventory pages must be **separate from** the **Schedules III – V** inventory pages • Name of each controlled substance inventoried • The finished form of each substance • The number of dosage units or volume of each finished form in each commercial container • The number of commercial containers of each finished form • The total count of the substance • All controlled substances are counted, including those in emergency boxes and will call bins **Date of Current Inventory: 5/1/25** (taken within 2 years of last inventory)	☒	☐	☐
NRS 28-410(4)	21. All controlled substances are properly stored.	☒	☐	☐
CFR 1306.05 NRS 28-414 NRS 28-414.01 NRS 71-2478	22. All prescriptions contain the required information prior to being filled.	☒	☐	☐
NRS 28-414.01 NRS 71-2478 CFR 1306.22	23. All refill requirements for prescriptions are compliant.	☒	☐	☐
CFR 1306.13 CFR 1306.23 NRS 28-414 NRS 28-414.01	24. Partial fillings of controlled substances are recorded and dispensed appropriately.	☐	☐	☒
CFR-1306.11(d)(1,2,3,4) NRS 28-414	25. All emergency Schedule II prescription procedures are followed. Only direct verbal authorization from the prescribing practitioner is allowed.	☐	☐	☒

Section Cited	Requirement	C	NC	NA
NRS 28-414 NRS 28-414.01 CFR 1306.05(d)	26. All requirements for filling electronic prescriptions (e-prescribing) and faxed prescriptions are followed. A manual "wet" signature is required for all written or faxed controlled substance prescriptions.	☒	☐	☐
NRS 28-414.03 NRS 28-415 NRS 38-2867.01 NRS 71-2451, 2479 CFR 1306.14	27. All prescription containers are properly labeled.	☒	☐	☐
NRS 38-28,108 through NRS 38-28,116	28. The pharmacy is compliant with the Drug Product Selection Act.	☒	☐	☐
NRS 28-414.03 CFR 1304.04(h)	29. A two or three file system for prescriptions is used and maintained.	☒	☐	☐
NRS 71-2410 through NRS 2417	30. Proper records are maintained for Emergency Drug Box use including: a. Receipt upon delivery signed by appropriate long term care staff b. Proof of use forms c. List of emergency box drugs are identical to the list on the exterior of the emergency box d. Pharmacy has policies and procedures for use of electronic or automated emergency boxes Controlled substance drugs cannot be removed from the Emergency Drug Box until the pharmacy receives a valid prescription from the practitioner.	☐	☐	☒
NRS 38-2847 NRS 38-2866.01 NRS 38-2890 thru NRS 38-2896 172 NAC 128-003.03 172 NAC 128-006.03	31. All requirements and documentation are met for the utilization of Pharmacy Technicians, including: a. Pharmacist supervision of pharmacy technicians and/or pharmacist intern ratio does not exceed 1:4 b. All pharmacy technician acts, tasks, or functions related to the practice of pharmacy are verified c. All technicians are registered with NE DHHS d. All technicians are certified, as required	☒	☐	☐
NRS 38-2891	32. Any pharmacy technician performing immunizations are compliant with all requirements and are supervised as required.	☐	☐	☒
175 NAC 8-007.02	33. Pharmacy has written disaster preparedness policies and procedures.	☒	☐	☐
NRS 38-2836.01 NRS 38-2867.03	34. The pharmacy is compliant with "Practice Agreement" requirements: a. A copy of the agreement with written protocols is available for review by the Department b. Practice agreements and written protocol must be signed by the practitioner with independent prescribing authority and participating pharmacists c. Practice agreements and written protocols must be reviewed, signed and dated at least every 24 months	☐	☐	☒

Section Cited	Requirement	C	NC	NA
NRS 38-2867.01 USP 795	35. The pharmacy is compliant with USP 795 (non-sterile compounding) including: a. Master Formulation and Compounding Records b. Label shall include the beyond use date and storage conditions c. Compliant with USP 800	☐	☐	☒
NRS 38-2867.01 USP 797	36. The pharmacy is compliant with USP 797 (sterile compounding) and USP 800.	☐	☐	☒
NRS 28-456 through NRS 462 CFR 1314	37. The pharmacy is compliant with all State and Federal regulations pertaining to the retail sale of scheduled listed chemical products/methamphetamine precursors, including: a. A purchaser signature logbook or electronic signature pad that displays the warning listed under Section 1001 Title 18, US Code b. Records of training and annual self-certification c. Name or initials of the seller who sold the product is submitted to the exchange	☐	☐	☒
NRS 71-7444(2)(d) NRS 71-7454(1)	38. The sale, purchase or trade of a prescription drug for emergency medical reasons or for a practitioner to use for routine office procedures does not exceed five percent of sales.	☒	☐	☐
NRS 71-7444; NRS 71-7454	39. All prescription drugs purchased or received are from entities licensed under the Nebraska Wholesale Drug Distributor Act, with exceptions in 71-7444 or 71-7454.	☒	☐	☐
NRS 38-2867.01	40. Compounded drugs are not being purchased from a 503B facility.	☐	☐	☒
NRS 71-2444 through 71-2452	41. Pharmacy has all required policies and procedures for use of an automated medication system.	☐	☐	☒
38-2817 38-2818 71-2465 71-2466	42. Prescriptions awaiting pick-up or delivery are ONLY stored at a licensed pharmacy.	☒	☐	☐

STATEMENT OF COMPLIANCE PAGE

For each item not in compliance, please list below:

a) The item number that is not in compliance;
b) Why it is not in compliance;
c) How the deficiency will be corrected; and
d) How long it will take to do so

2026 Random Inspection: -----

a)

b)

c)

d)

----- ----- -----

a)

b)

c)

d)

----- ----- -----

a)

b)

c)

d)

----- ----- ----

a)

b)

c)

d)

Inspector's Notes:
- This pharmacy dispenses specialty drugs and is located next to Amber Specialty Pharmacy
- This pharmacy does not stock, dispense or sell any CII controlled substances or scheduled listed chemicals. Spravato is only controlled substance dispensed from this pharmacy.
- Dr. Helser is generally the only pharmacist working under this pharmacy license but does share staff with Amber Specialty Pharmacy.

NEBRASKA
Good Life. Great Mission.
DEPT. OF HEALTH AND HUMAN SERVICES

Jim Pillen, Governor

Public Health Licensure Unit
Certification of Licensure

This certificate serves as primary source verification of licensure in the State of Nebraska as of the close of the business day before 7/ 1/2026.

Name:	HYVACS, LLC dba Hy-Vee Pharmacy Solutions
Owner:	Hy-Vee, Inc
Address:	10004 S 152nd St Ste C, Omaha, NE
Type:	Community Pharmacy License
Number:	3010
Status:	Active
Issued:	05/29/2014
Expiration:	07/01/2027

Disciplinary/Non-Disciplinary Information:

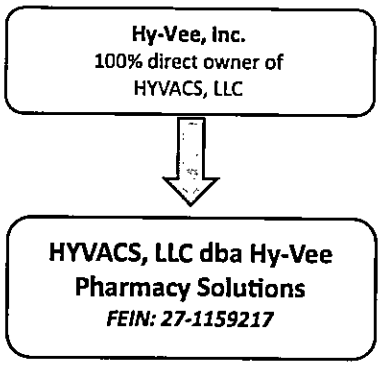
No disciplinary/non-disciplinary actions taken against this license.

If you have questions about this information, please contact the Licensure Unit at (402) 471-2115 or DHHS.LicensureUnit@nebraska.gov.

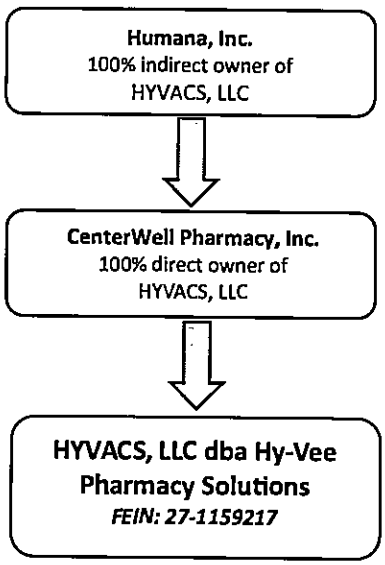
HYVACS, LLC dba Hy-Vee Pharmacy Solutions

Ownership Organization

Pre-Transaction Ownership



Post-Transaction Ownership



Humana, Inc. is a publicly traded company. A full list of Humana, Inc.'s institutional shareholders can be found in the company's annual 10K report that is filed with the SEC.

QB\470290.00082\103393234.1

4QQ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: D/B/A Baton Rouge General Compounding Pharmacy

Physical Address: 9001 Summa Ave

City: Baton Rouge State: LA Zip: 70809

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 225-387-7627 Toll Free # (NAC 639.708, NRS 639.23286): 833-727-5433

Fax: 225-387-7625 Contact Email: compoundpharmacy@brgeneral.org

Website: https://www.brgeneral.org/patient-center/pharmacy-services

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Iver O. Vandiver II

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23672

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Iver Vandiver II	NV Pharmacist Registration #: 23672
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Louisiana

Parent Company (if any): General Health System

Corporation/Organization Name: Baton Rouge General Medical Center

Mailing Address: 8585 Picardy Ave

City: Baton Rouge State: LA Zip: 70809

Telephone: 225-237-1645 Email: ken762@brgeneral.org

Contact Person Name: Kendall Johnson, CFO

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Chief Financial Officer (title) for BRG Compounding Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Kendall Johnson

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

8/3/2026

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Iver O. Vandiver II hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Clinical Manager (title) for BRG Compounding Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 3rd day of August, 2026

Notary Public
#140372

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

KENDALL A. JOHNSON

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

Date 8/3/2021

Board Use Only	Date Received: 9/1/21	Amount: $500 ck 70013169

Baton Rouge General

Ownership

General Health System (Parent company)
EIN: 72-0475545 Owns 100% of BRGMC; No shareholders/no individuals hold interest

Baton Rouge General Medical Center (Legal entity, non-profit corporation)
EIN: 72-1025017
D/B/A Baton Rouge General Compounding Pharmacy (Trade name)

Corporate Officers

Edgardo Tenreiro, *President/CEO*
Kendal Johnson, *Vice-President/CFO*

Retail Pharmacy

Baton Rouge General Compounding Pharmacy
9001 Summa Ave, Baton Rouge, LA 70809
Pharmacy #: 225-387-7627
Fax #: 225-387-7625
Toll free #: 833-727-5433
Email: compoundpharmacy@brgeneral.org

LA BOP: PHY.007151-IR
NPI: 1023491131
NCPDP: 1938731
NABP: 2013711

State of Louisiana
Secretary of State

COMMERCIAL DIVISION
225.925.4704

Fax Numbers
225.932.5317 (Admin. Services)
225.932.5314 (Corporations)
225.932.5318 (UCC)

Name	Type	City	Status
GENERAL HEALTH SYSTEM	Non-Profit Corporation	BATON ROUGE	Active

Previous Names

GENERAL HEALTH, INC. (Changed: 1/5/1995)

BATON ROUGE GENERAL HOSPITAL (Changed: 5/4/1984)

Business: GENERAL HEALTH SYSTEM
Charter Number: 01600010N
Registration Date: 7/9/1945

Domicile Address

8585 PICARDY AVE.
BATON ROUGE, LA 70809

Mailing Address

ATTN TAX DEPT
8490 PICARDY AVE.
BATON ROUGE, LA 70809

Status

Status: **Active**
Annual Report Status: **In Good Standing**
File Date: 7/9/1945
Last Report Filed: 8/13/2026
Type: Non-Profit Corporation

Registered Agent(s)

Agent: KENDALL JOHNSON
Address 1: C/O 8585 PICARDY AVE.
City, State, Zip: BATON ROUGE, LA 70809
Appointment Date: 7/2/2015

Agent: COREY DOUGHTY
Address 1: 8490 PICARDY AVE SUITE 100
City, State, Zip: BATON ROUGE, LA 70809
Appointment Date: 8/26/2016

Officer(s)

Additional Officers: No

Officer: KENDALL JOHNSON

Title:	Vice-President
Address 1:	C/O 8585 PICARDY AVE.
City, State, Zip:	BATON ROUGE, LA 70809

Officer:	EDGARDO TENREIRO
Title:	President
Address 1:	8585 PICARDY AVE.
City, State, Zip:	BATON ROUGE, LA 70809

Mergers (1)

Filed Date	Effective Date:	Type	Charter#	Chater Name	Role
1/4/1988	**1/4/1988**	**MERGE**	**01600010N**	**GENERAL HEALTH SYSTEM**	**SURVIVOR**
			33127990D	MEDICAL PERSONNEL POOL OF BATON ROUGE, INC	NON-SURVIVOR

Amendments on File (18)

Description	Date
Amendment	1/22/1958
Amendment	1/27/1964
Amendment	3/5/1969
Amendment	5/13/1969
Amendment	1/1/1970
Amendment	4/8/1971
Amendment	1/13/1975
Amendment	6/10/1976
Amendment	4/5/1982
Name Change	5/4/1984
Restated Articles	10/1/1984
Merger	1/4/1988
Name Change	1/5/1995
Amendment	1/12/1996
Amendment	6/24/2008
Domicile, Agent Change or Resign of Agent	12/27/2013
Appointing, Change, or Resign of Officer	8/26/2016
Domicile, Agent Change or Resign of Agent	8/26/2016

Print

State of Louisiana
Secretary of State

COMMERCIAL DIVISION
225.925.4704

Fax Numbers
225.932.5317 (Admin. Services)
225.932.5314 (Corporations)
225.932.5318 (UCC)

Name	Type	City	Status
BATON ROUGE GENERAL MEDICAL CENTER	Non-Profit Corporation	BATON ROUGE	Active

Previous Names

Business: BATON ROUGE GENERAL MEDICAL CENTER
Charter Number: 34120863N
Registration Date: 8/15/1983

Domicile Address

8585 PICARDY AVE.
BATON ROUGE, LA 70809

Mailing Address

ATTN : TAX DEPT
8490 PICARDY AVE.
BATON ROUGE, LA 70809

Status

Status: **Active**
Annual Report Status: **In Good Standing**
File Date: 8/15/1983
Last Report Filed: 8/13/2026
Type: Non-Profit Corporation

Registered Agent(s)

Agent:	KENDALL JOHNSON
Address 1:	8585 PICARDY AVE.
City, State, Zip:	BATON ROUGE, LA 70809
Appointment Date:	7/29/2015

Agent:	COREY DOUGHTY
Address 1:	8490 PICARDY AVE
City, State, Zip:	BATON ROUGE, LA 70809
Appointment Date:	8/29/2016

Officer(s)

Additional Officers: No

Officer:	KENDALL JOHNSON
Title:	Vice-President
Address 1:	8585 PICARDY AVE.

City, State, Zip:	BATON ROUGE, LA 70809

Officer:	EDGARDO TENREIRO
Title:	President
Address 1:	8585 PICARDY AVE
City, State, Zip:	BATON ROUGE, LA 70809

Mergers (2)

Filed Date	Effective Date:	Type	Charter#	Chater Name	Role
9/18/1998	**9/18/1998**	**MERGE**	**34120863N**	**BATON ROUGE GENERAL MEDICAL CENTER**	**SURVIVOR**
			34416439N	BATON ROUGE GENERAL HEALTH CENTER	NON-SURVIVOR
8/3/2015	**8/1/2015**	**MERGE**	**34120863N**	**BATON ROUGE GENERAL MEDICAL CENTER**	**SURVIVOR**
			40487946K	BATON ROUGE RADIOLOGY IMAGING CENTER, L.L.C.	NON-SURVIVOR

Amendments on File (9)

Description	Date
Amendment	1/5/1984
Amendment	1/12/1996
Disclosure of Ownership	5/21/1998
Merger	9/18/1998
Amendment	12/3/2004
Amendment	6/24/2008
Disclosure of Ownership	5/25/2010
Domicile, Agent Change or Resign of Agent	12/27/2013
Merger	8/3/2015

Print

Nancy Landry
Secretary of State

State of Louisiana
Secretary of State

COMMERCIAL DIVISION
225.925.4704

Fax Numbers
225.932.5317 (Admin. Services)
225.932.5314 (Corporations)
225.932.5318 (UCC)

Trade Name Details

Type(s) Registered: TRADE NAME
Registered Name: BATON ROUGE GENERAL COMPOUNDING PHARMACY
Applicant: BATON ROUGE GENERAL MEDICAL CENTER
8490 PICARDY AVE
STE. 300
BATON ROUGE, LA 70809
Type Of Business: HOSPITAL
Book #: 83-8240
Current Status: ACTIVE

Dates

Registration Date: 4/13/2026
Expiration Date: 4/13/2036
Date First Used: 1/1/2020
Date First Used (in La.): 1/1/2020

Current Classes

No Current Classes

Expired Classes

No Expired Classes

Amendments On File

No Amendments on file

Print

UNITED STATES OF AMERICA

State of Louisiana

Nancy Landry

SECRETARY OF STATE

As Secretary of State of the State of Louisiana, I do hereby Certify that

BATON ROUGE GENERAL MEDICAL CENTER

A corporation domiciled in BATON ROUGE, LOUISIANA,

Filed charter and qualified to do business in this State on August 15, 1983,

I further certify that the records of this Office indicate the corporation has paid all fees due the Secretary of State, and so far as the Office of the Secretary of State is concerned is in good standing and is authorized to do business in this State as a Non-Profit Corporation.

In testimony whereof, I have hereunto set my hand and caused the Seal of my Office to be affixed at the City of Baton Rouge on,

June 23, 2026

Nancy Landry

Secretary of State

Web 34120863N

STATE OF LOUISIANA · UNION · JUSTICE · CONFIDENCE · SECRETARY OF STATE

Certificate ID: 12215076#ESL73

To validate this certificate, visit the following web site, go to Business Services, Search for Louisiana Business Filings, Validate a Certificate, then follow the instructions displayed.
www.sos.la.gov

UNITED STATES OF AMERICA

State of Louisiana

Nancy Landry

SECRETARY OF STATE

As Secretary of State of the State of Louisiana, I do hereby Certify that

BATON ROUGE GENERAL MEDICAL CENTER, located at 8490 PICARDY AVE, STE. 300, BATON ROUGE, LA 70809,

Has filed for record in this department an application for the trade name

BATON ROUGE GENERAL COMPOUNDING PHARMACY

Which was first used in the State of Louisiana on January 01, 2020,

Said application was filed and recorded in this Office on April 13, 2026, which recordation is for a term of ten years from the date hereof.

In testimony whereof, I have hereunto set my hand and caused the Seal of my Office to be affixed at the City of Baton Rouge on,

April 14, 2026

Nancy Landry

Secretary of State

LH 83-8240

STATE OF LOUISIANA · UNION · JUSTICE · CONFIDENCE · SECRETARY OF STATE

Certificate ID: 12182025#DFG62

To validate this certificate, visit the following web site, go to **Business Services, Search for Louisiana Business Filings, Validate a Certificate,** then follow the instructions displayed.
www.sos.la.gov

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Baton Rouge General Compounding Pharmacy

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 9001 Summa Ave

City: Baton Rouge State: LA Zip: 70809

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 225-387-7627 Website: https://www.brgeneral.org/patient-center/pharmacy-services

Licensing Company Email: compoundpharmacy@brgeneral.org

Section 2: Personal Information

First: Iver Middle: O'Neal Last: Vandiver

Alias(es, nicknames, name changes, etc.): Iver O Vandiver II

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Baton Rouge State: LA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Samford University		08/13 - 05/17	
Address	**City**	**State**	**Zip**
800 Lakeshore Drive	Birmingham	AL	35229
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Mississippi State University		08/08 - 12/11	
Address	**City**	**State**	**Zip**
75 B.S. Hood Drive	Mississippi State	MS	39762
Diploma/Degree obtained, if any			
B.S. - Kinesiology			

School Name		From - To (MM/YY – MM/YY)	
Alcorn Central High School		08/04 - 05/08	
Address	**City**	**State**	**Zip**
81 County Road 254	Glen	MS	38846
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	
06/25 - Present	[redacted]	Baton Rouge	LA	[redacted]
03/24 - 06/25		Baton Rouge	LA	
06/22 - 03/24		Memphis	TN	
05/21 - 06/22		Cordova	TN	
05/20 - 05/21		Rocky Mount	NC	
05/17 - 05/20		Corinth	MS	
01/13 - 05/17		Glen	MS	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Baton Rouge General Medical Center			03/24 - Present	
Business Address		**City**	**State**	**Zip**
8585 Picardy Ave		Baton Rouge	LA	70809
Phone	**Title**		**Number of Employed Hours**	
225-387-7627	Operations Supervisor & Clinical Manager		5050	
Description of Duties				
Inpatient operations supervisor and clinical pharmacist; Clinical manager, specialty pharmacy & PIC for several non-resident permits				

Business Name			From - To (MM/YY – MM/YY)	
CVS Specialty			05/21 - 03/24	
Business Address		**City**	**State**	**Zip**
8370 Wolf Lake Dr, STE 107		Bartlett	TN	38133
Phone	**Title**		**Number of Employed Hours**	
901-385-4100	Supervisor, Pharmacy Operations		7200	
Description of Duties				
Operations supervisor, PIC for several non-resident permits				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, Iver O'Neal Vandiver II **, certify that as the designated representative for**

Baton Rouge General Medical Center, D/B/A Baton Rouge General Compounding Pharmacy ,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. IOV I am at least 21 years of age;
3. IOV I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. IOV I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. IOV I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. IOV I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. IOV I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Iver Vandiver II

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/27/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Iver Vandiver II

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/27/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Louisiana, ss. County of East Baton Rouge

I, Iver Vandiver II, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/27/2026

Date

Subscribed and Sworn to before me this 27th day of August 2026

Notary Public Signature

(Seal)

Louisiana Board of Pharmacy

3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov ~ Telephone: 225.925.6496 ~ E-Mail: info@pharmacy.la.gov

Pharmacy Inspection Report

Permit Data	Report No. 048	Inspected by: Aaron	Territory: Aaron	Date: 3/25/2026

Reason for Visit: ☐ Initial Survey ☒ Service Review ☐ Follow-Up Survey ☐ Compliance Check

1. Pharmacy Name	2. Permit No.	3. CDS License	4. Classification	5. Renewal Yr.
Baton Rouge General Compounding Pharmacy	7151	46770	IR	2026

6. Physical Address	7. City, State, Zip	8. CSP License
9001 Summa Ave	Baton Rouge, LA 70809	N/A ☒

9. Phone No.	10. Authorized email address for report:	11. Rx Software	12. DEA No.	DEA Expiration
225-387-7627	des708@brgeneral.org; bre166@brgeneral.org	Rx-30	[redacted]	7/31/27

13. Store Hours	14. Pharmacy Hours
Clinic Hours 8a-5p M-F; closed S/S N/A ☐	8a-4p M-F; Closed S/S

15. Pharmacist-In-Charge Name	16. PIC License No.	17. Renewal Year	18. PIC Present During Inspection?
De'Shanae R. Dean	21847	2026	Yes ☒ No ☐

	Professional and Occupational Standards		
19	Are permit credentials current and active? LA R.S. 37:1201	Yes ☒ No ☐ N/A ☐	
20	Does permit staff administer immunizations? LA R.S. 37:1218, 1218.1; LAC 46:LIII.521	No	
21	Does permit mail or deliver prescriptions to patients?	Yes	Mail and Deliver
	If yes, are prescriptions delivered or mailed to other states?	Yes	Mail and Deliver
22	Is permit licensed in any state other than Louisiana? If yes, list.	Yes	See below
23	Does permit provide "office use" medication to providers?	No	
24	Does the permit participate in a drug take-back program?	No	
	If yes, is it properly registered with the DEA? 21 CFR Part 1317	Yes ☐ No ☐ N/A ☒	
25	Does the prescription department provide sufficient space, fixtures, supplies and equipment commensurate with the nature and scope of the pharmacy's practice? LAC 46:LIII.1103.A	Yes ☒ No ☐ N/A ☐	
26	Is temperature in drug storage area within USP standards? LAC 46:LIII.1103.A, E	Yes ☒ No ☐ N/A ☐	
27	Is permit clean and orderly? Are medications and supplies stored appropriately? LAC 46:LIII.1103.A	Yes ☒ No ☐ N/A ☐	
28	Is permit well-lit? LAC 46:LIII.1103.A	Yes ☒ No ☐ N/A ☐	
29	Is a sink providing hot and cold running water located within the prescription department? LAC 46:LIII.1103.C	Yes ☒ No ☐ N/A ☐	
30	Is refrigerator and/or freezer temperature within USP standards? (Document temperature) LAC 46:LIII.1103.E	Yes ☒ No ☐ N/A ☐	5.1 C
31	Does the permit have a working security system? LAC 46:LIII.1103.F	Yes ☒ No ☐ N/A ☐	
32	Does the permit have general security measures in place? LAC 46:LIII.1103.F	Yes ☒ No ☐ N/A ☐	
33	Does the permit have access to required references? LAC 46:LIII.1103.H	Yes ☒ No ☐ N/A ☐	
34	Are misbranded, non-labeled, or expired medications removed from active inventory? LAC 46:LIII.2501	Yes ☒ No ☐ N/A ☐	
35	Does the permit maintain any off-site inventory, such as an EDK or AMS? If yes, list.	No	
36	Does the permit maintain a Policy & Procedure manual? LAC 46:LIII.1105.D	Yes ☒ No ☐ N/A ☐	
37	Are credentials of licensed personnel current and active? LA R.S.37:1201	Yes ☒ No ☐ N/A ☐	
38	Is PST:PNT/CPT/PTC ratio compliant with regulations? (Document ratio) LAC 46:LIII.709, 907	Yes ☒ No ☐ N/A ☐	1 PST, 1 CPT
39	Does permit provide patient counseling? LAC 46:LIII.517	Yes ☒ No ☐ N/A ☐	
40	Does the permit utilize a method for the positive identification of a pharmacist as defined in LAC Title 46:1119?	Yes ☒ No ☐ N/A ☐	Manual Pharmacist Register
41	Are required permit records retained on site?	Yes	
42	Does permit utilize CSOS or paper DEA Form 222?	CSOS and Paper	
	Are DEA Forms 222 properly executed? 21 CFR Part 1305	Yes ☐ No ☐ N/A ☒	No paper 222 forms used in past 2 years.
	List wholesalers and reverse distributors used:		Morris & Dickson, Cencora, Inmar
43	Are CDS invoices retrievable and dated? 21 CFR 1304.21, 1304.22, LAC 46:LIII.2735	Yes ☒ No ☐ N/A ☐	
44	Are CDS inventories conducted as required? (Annual, PIC Change, Theft/Loss) List dates LAC 46:LIII.2733	Yes ☒ No ☐ N/A ☐	10/3/24, 9/4/25
45	Are CDS medications stored in a manner compliant with LAC Title 46:2717?	Yes ☒ No ☐ N/A ☐	
46	Is required information present on CDS prescriptions? LAC 46:LIII.2745	Yes ☒ No ☐ N/A ☐	
47	Pharmacist on-duty confirms an understanding of the Pharmacist's Corresponding Responsibility. LAC 46:LIII.2745.B,C	Yes	
48	Are prescriptions filed in a manner compliant with laws and regulations? LAC 46:LIII.1123	Yes ☒ No ☐ N/A ☐	
49	Does the permit perform non-sterile compounding? LAC 46:LIII.2535	No	N/A
50	Does the permit perform sterile compounding? LAC 46:LIII.2535	No	N/A

Louisiana Board of Pharmacy

3388 Brentwood Drive, Baton Rouge, Louisiana 70809-1700
www.pharmacy.la.gov ~ Telephone: 225.925.6496 ~ E-Mail: info@pharmacy.la.gov

Pharmacy Inspection Report

Permit Data	Report No. 048	Inspected by: Aaron	Territory: Aaron	Date: 3/25/2026

Pharmacy Name	Permit No.	CDS License	Classification	Renewal Yr.
Baton Rouge General Compounding Pharmacy	7151	46770	IR	2026

51. Pharmacy Staff Present During Inspection	License No.	Renewal Year
Pamela S. Smith	CPT.002156	2025-26

52. Prior Inspection Date:	53. Deficiencies/Non-Compliance on Prior Inspection	54. Correction(s) Observed
10/3/24	None	N/A

55. Comments NOTE: A finding of satisfactory compliance is not indicative of a detailed inspection/investigation and does not exclude the permit and/or staff from possible future violations of compliance.
>PST Dragomer will review that this inspection report be emailed to dan708@bellsouth.net and bar1868@gmail.com
>Discussed overall security of pharmacy department. Also discussed ensuring all of policy and procedures are implemented and followed to date, employee diversion and facilitate early detection of any suspicious activity involving controlled dangerous substances.
>All Board licensed persons must notify the Board office within 10 days of a change of mailing address or primary place of employment; change must be made by logging into the appropriate account on the Board of Pharmacy website.
>Reviewed that according to federal and state regulations, prescriptions for a controlled substance in Schedules II, III, IV, or V expire one year after the date of issue and the number of refills are not limited. Also discussed LAC 46:LIII.2511.R, which states that a pharmacy may not cancel the remainder of an unreserved prescription unless required by law or rule, requested by the prescriber, or the prescription is transferred to another pharmacy.
>Permit currently holds state licenses in Mississippi (1988167, exp 12/31/27), Idaho (license 7001751, exp 11/30/26), and Texas (1993128, exp 12/31/26). Permit is transitioning to a Specialty Pharmacy and currently holds URAC and ACHC accreditation.
>This inspection is due to a relocation. Permit plans to close old location (7760 Florida Blvd in Baton Rouge) at 4:00pm on 4/3/26 and open in new location (noted above) at 8:00am on 4/6/26. PST Dragomer will notify Carley Leach (Board Approved) to go over and myself if the relocation is delayed.

Dr. Shannon R. Dean, PST
Authorized Signature & Title

Cory D. Aaron, PhTh
Compliance Officer, Louisiana Board of Pharmacy

Brett Dragomer, PST
Authorized Signature & Title

Louisiana Board of Pharmacy Online eLicense Website

The Louisiana Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, and further, performs daily updates to the website. Therefore, the website is a secure and primary source for credential verification, as authentic as a direct inquiry to the Board.

Lookup Detail View

Name and Address

Name	PublicAddress
Baton Rouge General Compounding Pharmacy	9001 Summa Ave Baton Rouge, LA 70809-3726

Credential Information with supervision

License	License Type	Issue Date	Expiration Date	Status	Pharmacist In Charge
PHY.007151-IR	Pharmacy - Community ~ Independent	07/22/2015	12/31/2026	Current, without restriction or limitation	De'Shanae R. Dean

List of Current Employees

Name	License	License Type	Expiration Date	Status
Angele Williams	CPT.009508	Certified Pharmacy Technician	06/30/2027	ACTIVE
Bailey Dupre Hood	PST.024978	Pharmacist	12/31/2026	ACTIVE
Cleo J. Solete	CPT.012019	Certified Pharmacy Technician	06/30/2027	ACTIVE
Dana Godso Monte	CPT.004508	Certified Pharmacy Technician	06/30/2027	ACTIVE
De'Shanae R. Dean	PST.021847	Pharmacist	12/31/2026	ACTIVE
George L. Munn Jr.	PST.009445-G	Pharmacist - Gold	12/31/2026	ACTIVE
Hannah June Milton	PST.024951	Pharmacist	12/31/2026	ACTIVE
Hayley Ann Harvey	CPT.018798	Certified Pharmacy Technician	06/30/2027	ACTIVE
Iver O. Vandiver II	PST.023832	Pharmacist	12/31/2026	ACTIVE
Ja'nae S. Sanders	PST.021755	Pharmacist	12/31/2026	ACTIVE
Jessica T. Aucoin	PST.023450	Pharmacist	12/31/2026	ACTIVE
Kellie A. Cooley	PST.023045	Pharmacist	12/31/2026	ACTIVE
Lisa E. Bergeron	PST.018549	Pharmacist	12/31/2026	ACTIVE
Lisa F. LaCour	PST.015444	Pharmacist	12/31/2026	ACTIVE
Pamela S. Smith	CPT.002156	Certified Pharmacy Technician	06/30/2027	ACTIVE
Patrice L Williams	CPT.014467	Certified Pharmacy Technician	06/30/2027	ACTIVE
Ranisha R. Lanieux	CPT.010320	Certified Pharmacy Technician	06/30/2027	ACTIVE
Sejal Ghanshyam Patel	PST.017529	Pharmacist	12/31/2026	ACTIVE

Name	License	License Type	Expiration Date	Status
Shawn R. Kelley	PST.016340	Pharmacist	12/31/2026	ACTIVE
Sundee Corban	CPT.005740	Certified Pharmacy Technician	06/30/2027	ACTIVE
Wendy T. W. Blackston	PST.015445	Pharmacist	12/31/2026	ACTIVE

CDS Schedules and Restrictions

I	II	II-N	III	III-N	IV	V	Restrictions	Alternative Privileges

Generated on: 8/4/2026 11:29:38 AM

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: Baton Rouge General Compounding Pharmacy

Address: 9001 Summa Ave

City: Baton Rouge State: LA Zip: 70809

I hereby authorize the Louisiana Board of Pharmacy to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant [signature]

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
PHY.007151-IR	Active-current; Valid for Practice	07/22/2015	12/31/2026

Has this license been encumbered in any way?	Type of Encumbrance: (if any) N/A
☐ Yes ☑ No	☐ Revoked ☐ Surrendered ☐ Limited ☐ Suspended ☐ Restricted ☐ Probation Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	☐ Yes ☑ No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	☐ Yes ☑ No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	☐ Yes ☑ No
Has applicant met all licensing requirements of your state? (If no, please explain)	☑ Yes ☐ No

Signature of State Official	Title	State	Date	State Seal
Cailey Leach	Licensing Analyst II	LA	08/06/2026	

Baton Rouge General

8/27/2026

RE: Personal History Record Application

To whom it may concern,

Baton Rouge General Medical Center is non-profit Corporation domiciled in Louisiana General Health System's full ownership. There are no shareholders/stockholders, no partners, nor a sole owner. Kindly advise if additional information is needed for the application to be considered and identify which individuals in the organization would be appropriate for consideration with regard to your application format.

Iver O Vandiver II, PharmD, MPH
Clinical Manger, BRG Compounding Pharmacy
Baton Rouge General Medical Center

Baton Rouge General

8/27/2026

RE: Nevada PMP

To whom it may concern,

Baton Rouge General Compounding Pharmacy will not dispense nor ship controlled substances to any resident of the State of Nevada. Please advise if a waiver or additional information is needed for this application to be considered.

Iver O Vandiver II, PharmD, MPH
Clinical Manger, BRG Compounding Pharmacy
Baton Rouge General Medical Center

4RR

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 04652	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Specialty-mail order.	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Pantherx Specialty Pharmacy

Physical Address: 280 Moore Lane

City: Collierville State: TN Zip: 38017

Mailing Address (if different from physical address): N/A

City: _____ State: _____ Zip: _____

Telephone: (855) 726-8479 Toll Free # (NAC 639.708, NRS 639.23286): (855) 726-8479

Fax: (855) 246-3986 Contact Email: tnlicensing@pantherxrare.com

Website: www.pantherxrare.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Kevin Arrison

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24871

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Kevin Arrison	NV Pharmacist Registration #: 24871
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice, Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Pennsylvania

Parent Company (if any): Panther Specialty Holding Co.

Corporation/Organization Name: PANTHERx Specialty, LLC

Mailing Address: 24 Summit Park Drive, Suite 101

City: Pittsburgh State: PA Zip: 15275

Telephone: (855) 726-8479 Email: tnlicensing@pantherxrare.com

Contact Person Name: Kevin Arrison

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist-in-Charge (title) for PANTHERx Specialty, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Kevin Arrison

Print Name of Authorized Person

Kevin Arrison

Original signature of Authorized Person (copies or stamps not accepted)

9-3-26

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Kevin Arrison hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist-in-Charge (title) for PANTHERx Specialty, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 3rd day of September, 2026

Notary Public

LATASHA R JONES
STATE OF TENNESSEE
NOTARY PUBLIC
COUNTY OF SHELBY

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Snyder, Executive Chair

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

RAS

Original signature of Authorized Person (copies or stamps not accepted)

9/4/2026

Date

Board Use Only	Date Received: 9/14/26	Amount: 500.00/ V#574887

Pantherx Specialty Pharmacy

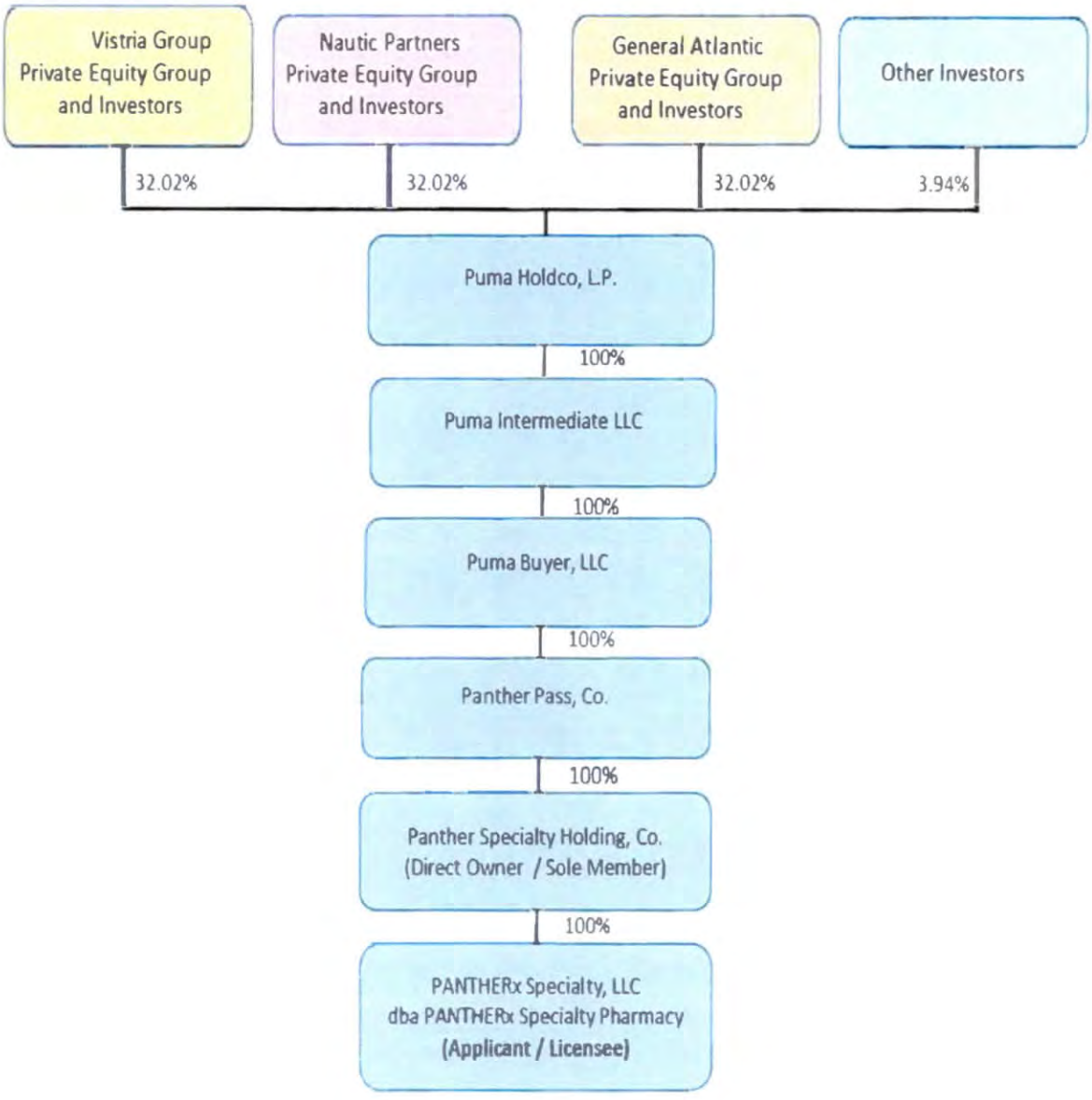
Ownership and Officers

Panther Specialty Holding Co. owns 100% of and is the parent company of PANTHERX Specialty LLC d/b/a Panther Specialty Pharmacy.

The officers of PANTHERX Specialty LLC d/b/a Panther Specialty Pharmacy are as follows:

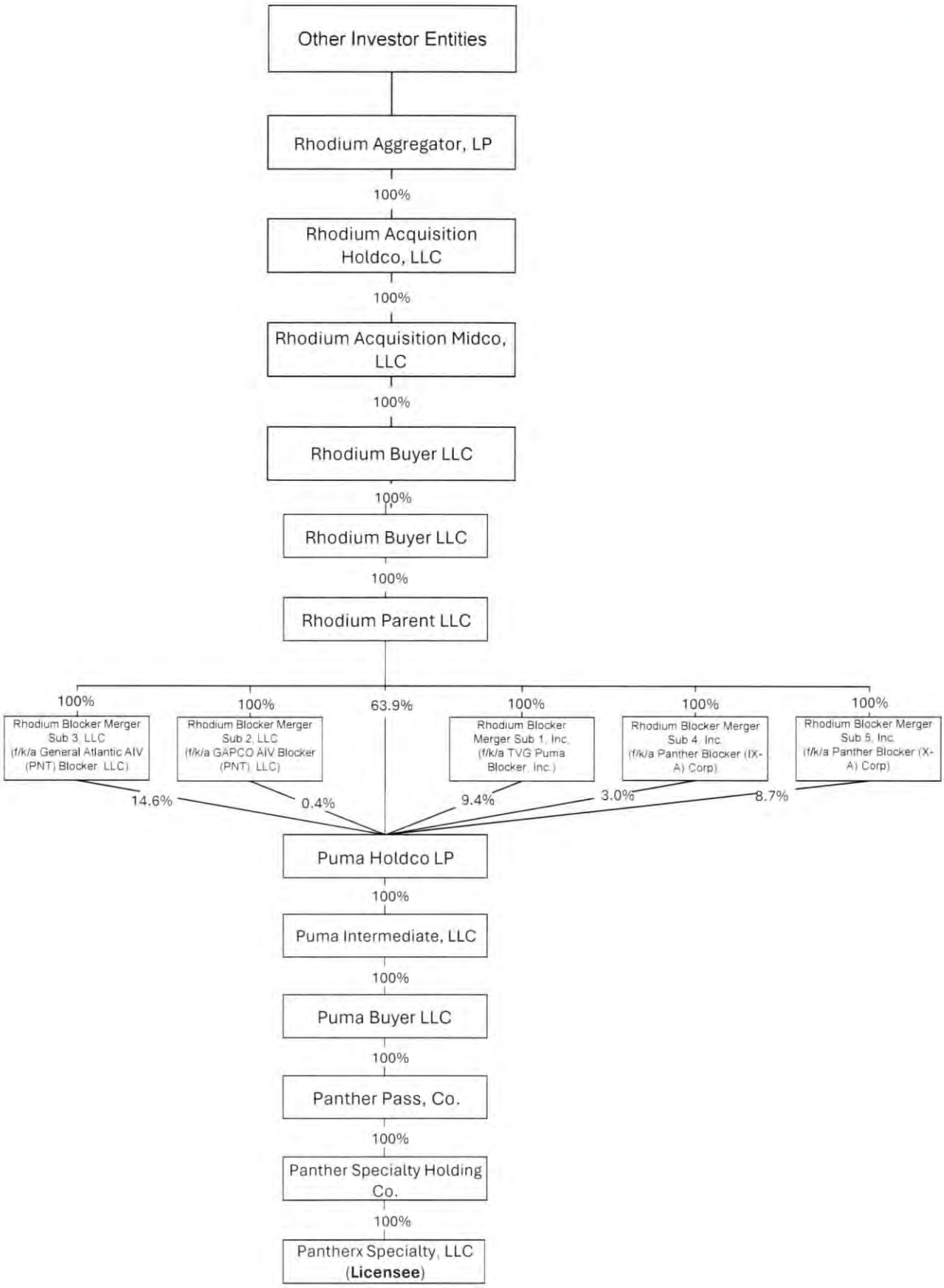
1. Bansi Nagji, Chief Executive Officer
2. Arik Moav, Chief Financial Officer
3. Robert Snyder, Executive Chair
4. Richard Faris, Chief Commercial and Clinical Officer

PANTHERx Specialty, LLC dba PANTHERx Specialty Pharmacy
Pre-Close Organizational Chart



Post-Closing Organisational Chart

CONFIDENTIAL



Division of Business and Charitable Organizations
Department of State
State of Tennessee
312 Rosa L. Parks Avenue, 6th Floor
Nashville, Tennessee 37243
Phone: 615-741-2286
tncab.tnsos.gov/portal/

Tre Hargett
Secretary of State

SARAH BARTH
1211 6TH AVE
NEW YORK, NY 10036, USA

07/25/2026

Request Type: Certificate of Existence/Authorization

Issuance Date: 07/25/2026

Request #: C2026082730

Document Receipt

Order Number: C2026082730		Verification #: F1A21DEC	
Receipt #: 2026-727996		Filing Fee:	$40.00
Payment: Credit Card - 3924722457			$40.00

Entity Name:	PANTHERX SPECIALTY, LLC		
SOS Control #:	001527538	Initial Filing Date:	04/02/2024
Entity Type:	Foreign Limited Liability Company (LLC)	Formation Locale:	PENNSYLVANIA
Status:	Active	Duration Term:	Perpetual
Fiscal Year Close:	December	Annual Report Due:	04/01/2027
Business County:	SHELBY		
Managed By:	Board Managed		
Obligated Member Entity:	No		

CERTIFICATE OF AUTHORIZATION

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

PANTHERX SPECIALTY, LLC

* is a Limited Liability Company formed in the jurisdiction set forth above and is authorized to transact business in this State;
* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;
* has filed the most recent annual report required with this office;
* has appointed a registered agent and registered office in this State;
* has not filed an Application for Certificate of Withdrawal.

Tre Hargett
Secretary of State

Verification #: F1A21DEC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler PANTHERx Specialty, LLC

Pharmacy/Wholesaler License # (if applicable) PH04652

Physical Address 280 Moore Lane

City Collierville State TN Zip 38017

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 855-726-8479 Website www.pantherxrare.com

Licensing Company Email tnlicensing@pantherxrare.com

Section 2: Personal Information

First Kevin Middle Tyler Last Arrison

Alias(es, nicknames, name changes, etc.) —

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Bartlett State TN Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	—	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)		
Union University College of Pharmacy	8/2012 – 5/2016		
Address: 1050 Union University Dr.	City: Jackson	State: TN	Zip: 38305
Diploma/Degree obtained, if any: PharmD			

School Name	From - To (MM/YY – MM/YY)		
Union University McAfee School of Business	~~8/2009 – 5/2012~~ 8/2015 – 5/2018		
Address: 1050 Union University Dr.	City: Jackson	State: TN	Zip: 38305
Diploma/Degree obtained, if any: MBA			

School Name	From - To (MM/YY – MM/YY)		
Austin Peay State University	8/2009 – 5/2012		
Address: 601 College St.	City: Clarksville	State: TN	Zip: 37044
Diploma/Degree obtained, if any: Associates			

School Name	From - To (MM/YY – MM/YY)		
Bolton Highschool	8/2005 – 5/2009		
Address: 7323 Brunswick Rd.	City: Arlington	State: TN	Zip: 38002
Diploma/Degree obtained, if any: Highschool diploma			

School Name	From - To (MM/YY – MM/YY		
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
7/2023 – present	[redacted]	Bartlett	TN	[redacted]
5/2016 – 7/2023	[redacted]	Bartlett	TN	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.500S) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Panther x Rare Pharmacy			From - To (MM/YY – MM/YY): 5/2025 – present
Business Address: 280 Moore LN	City: Collierville	State: TN	Zip: 38017
Phone: 855-726-8479	Title: Director, FulFillment Services		Number of Employed Hours: 2,720
Description of Duties: Direct pharmacy that fills 1,000 prescriptions per day via mail. Oversee staff of pharmacists and techs.			

Business Name: Walgreens			From - To (MM/YY – MM/YY): 8/2016 – 5/2025
Business Address: 8700 w Trail Lake Dr.	City: Memphis	State: TN	Zip: 38125
Phone: 901-309-1404	Title: Pharmacy Manager, District Manager		Number of Employed Hours: 16,040
Description of Duties: was Pharmacy manager ran several stores, filled and verified prescriptions. was then District manager in charge of 14 stores helping them to dispense prescriptions.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Kevin Arrison, **certify that as the designated representative for**

PANTHERx Specialty, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. KA I am at least 21 years of age;
3. KA I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. KA I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. KA I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. KA I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. KA I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kevin Arrison

Print Name (First, Last)

Kevin Arrison

Original Signature (electronic, copies or stamps not accepted)

9-3-26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kevin Arrison

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) — Date: 9-3-26

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Shelby

I, Kevin Arrison, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature — **Date**: 9-3-26

Subscribed and Sworn to before me this 3rd day of September, 2026

Notary Public Signature

LATASHA R JONES
STATE OF TENNESSEE
NOTARY PUBLIC
COUNTY OF SHELBY

(Seal)

Proprietary and Confidential - Not a public record pursuant to Section 7927.605 of the CPRA and 45 CFR Section 5.31

DEPARTMENT OF HEALTH
TENNESSEE BOARD OF PHARMACY
COMMUNITY INSPECTION
COMPLIANCE INSPECTION

PHARMACY: PantherRX Specialty Pharmacy	
STREET: 280 Moore Ln	
CITY: Collierville	ZIP: 38017
DATE OPENED:	TELEPHONE NO: (855) 726-8479
LICENSE NO.: 7321	EXPIRY DATE: 8/31/26
DEA NO.: FP4437932	EXPIRY DATE: 3/31/27
PHARMACIST IN CHARGE/Duty: Anthony Ashbrook	LIC NO.: 39088 / EXPIRY DATE: 4/30/27

Inspected by	Date
Derek Johnston	5/14/25

This Inspection Satisfactory: Yes ☑ No ☐

☐ Opening ☐ Relocation ☐ New Ownership ☐ Follow-up ☐ Counseling Compliance ☑ Periodic ☐ Remodeling

Compliance Yes	Compliance No	PERSONNEL
✓		1. Appropriate identification/Name Tags
N/A		2. D. Ph./Tech ration
✓		3. Personnel/apparel clean
N/A		4. Tech registry & Affidavit

Compliance Yes	Compliance No	PHYSICAL REQUIREMENTS
✓		5. Certificates Displayed
✓		6. RX Dept. - Sufficient Space/Counseling
✓		7 Fully enclosed when applicable
✓		8. Key Lockable/Key Control

Compliance Yes	Compliance No	DRUGS AND EQUIPMENT
✓		9. Dispensing area clean, orderly, well lighted
✓		10. Sink, hot and cold water
✓		11 Refrigeration
✓		12. References, periodicals
N/A ✓		13. Vials and closures (child-proof)
✓		14. Shelves and drug stock clean
N/A ✓		15. Drugs in-date
N/A		16. Labelscorrect on repackaging
✓		17. Legend drugs stored in RX Dept.
✓		18. Syringes/insulin, restricted products non-accessible

		19. RXs numerically filed
		☐ All C's together ☐ C-11's separate ☐ Multiple file method
		20. Patients identifiable
		21. Prescribers identifiable
N/A		22. New verbal RXs initialed by appropriate personnel
		23. Date of original dispensing
		24. Initials of dispensing D. Ph.
		25. Quantity dispensed indicated
		26. Appropriate Emergency C-11 RXs
		27. Computer labels applied appropriately to RXs
		28. Pharmacist Signature Log
		29. Daily Print Out

Compliance Yes	Compliance No	DRUG PRODUCT SUBSTITUTION
N/A		30. Authorization documented on Rx
N/A		31. Manufacturer indicated on Rx or System
N/A		32. Approved products used.

Compliance Yes	Compliance No	PATIENT COUNSELING
✓		33. Patient profiles
✓		34. Drug Utilization Review
✓		35. Patient Counseling

Compliance Yes	Compliance No	CONTROLLED SUBSTANCE RECORDS
		36. Readily retrievable
		37. All C-II records separate
	N/A	38. DEA Form 222 Copy 3 on hand & completed
N/A		39. Drug Receipt date on invoices
		40. Record of drug transfers
		41. ☐ Schedule V sales record book ☐ Methamphetamine Sales Log
		42. Last DEA Inventory (date) N/A
		42. Last Theft/loss report (date) N/A
✓		43. Access to Control Substance Monitoring Database

Pharmacy Hours: 8-5 M-F

ITEMS TO BE CORRECTED: **RESPONSE REQUIRED** YES ☐ NO ☑

Immediately
Needs Improvement
Within 30 Days

Remarks or Recommendations: ~~No controlled substances on site or anticipated~~ No controlled substances on site or anticipated

I Anthony Adam Ashbrook hereby acknowledge and understand all notations made on this report; and confirm that
Pharmacist Signature
I will notify the Board of Pharmacy within 30 days, in writing, of the correction of all deficiencies (If noted.)

15338835

State of Tennessee
Department of Health

Renewal No. 61950

Board of Pharmacy
Pharmacy

PANTHERX SPECIALTY LLC DBA PANTHERX SPECIALTY PHARMACY, 280 MOORE LANE, COLLIERVILLE, TN 38017

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 7821

EXPIRATION DATE: August 31, 2028

CONTROLLED SUBSTANCE REGISTRATION

John R. Dunn
Commissioner, Dept. of Health

Kenneth L. Putnam, Esq.
Assistant Commissioner, Health Licensure and Regulation

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
OFFICE OF HEALTH RELATED BOARDS
665 Mainstream Drive, Second Floor
Nashville, TN 37243
https://www.tn.gov/health/licensure.html

Board of Pharmacy
Pharmacy
1-800-778-4123 or

September 8, 2026

Nevada Board of Pharmacy
985 Damonte Ranch Pkwy., Ste. 206
Reno, NV 89521

TO WHOM IT MAY CONCERN:

This verification can be considered primary source. To expedite the verification process, this is the standard format used by the Tennessee Board of Pharmacy. We are pleased to furnish the following information from our files:

PROFESSION:	Pharmacy
NAME:	Pantherx Specialty LLC
ADDRESS:	dba Pantherx Specialty Pharmacy 280 Moore Lane Collierville, TN 38017
LICENSE NUMBER:	7821
ISSUE DATE:	August 16, 2024
EXPIRATION DATE:	August 31, 2028
CURRENT STATUS:	Licensed
STATUS DATE:	August 16, 2024
SPECIAL ENDORSEMENT:	Controlled Substance Registration

COMMENTS: There is no derogatory information in our files concerning this facilty.

Sincerely,

Tennessee Board of Pharmacy

VERFFACLTY

4SS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH 04087	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Specialty mail-order.	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Pantherx Specialty Pharmacy

Physical Address: 1120 Stevenson Mill Road, Suite 400

City: Coraopolis State: PA Zip: 15108

Mailing Address (if different from physical address): N/A

City: _____ State: _____ Zip: _____

Telephone: (855) 726-8479 Toll Free # (NAC 639.708, NRS 639.23286): (855) 726-8479

Fax: (855) 246-3986 Contact Email: licensing@pantherxrare.com

Website: www.pantherxrare.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Gregory Lucas

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23138

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Gregory Lucas	NV Pharmacist Registration #: 23138
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Pennsylvania

Parent Company (if any): Panther Specialty Holding Co.

Corporation/Organization Name: PANTHERx Specialty, LLC

Mailing Address: 24 Summit Park Drive, Suite 101

City: Pittsburgh State: PA Zip: 15275

Telephone: (855) 726-8479 Email: licensing@pantherxrare.com

Contact Person Name: Gregory Lucas

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist-in-Charge (title) for PANTHERx Specialty, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Gregory Lucas

Print Name of Authorized Person

Original Signature of Authorized Person (copies or stamps not accepted)

9/3/20

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Gregory Lucas hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist-in-Charge (title) for PANTHERx Specialty, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

Commonwealth of Pennsylvania
County of Allegheny

SUBSCRIBED AND SWORN TO
Before me, a notary public this 3rd day of September, 2026

Karen L Randall
Notary Public

Commonwealth of Pennsylvania - Notary Seal
Karen L. Randall, Notary Public
Allegheny County
My commission expires April 5, 2029
Commission number 1206384
Member, Pennsylvania Association of Notaries

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Snyder, Executive Chair

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

9/4/2026

Date

Board Use Only	Date Received: 9/14/26	Amount: 500.00/ V# 524888

Pantherx Specialty Pharmacy

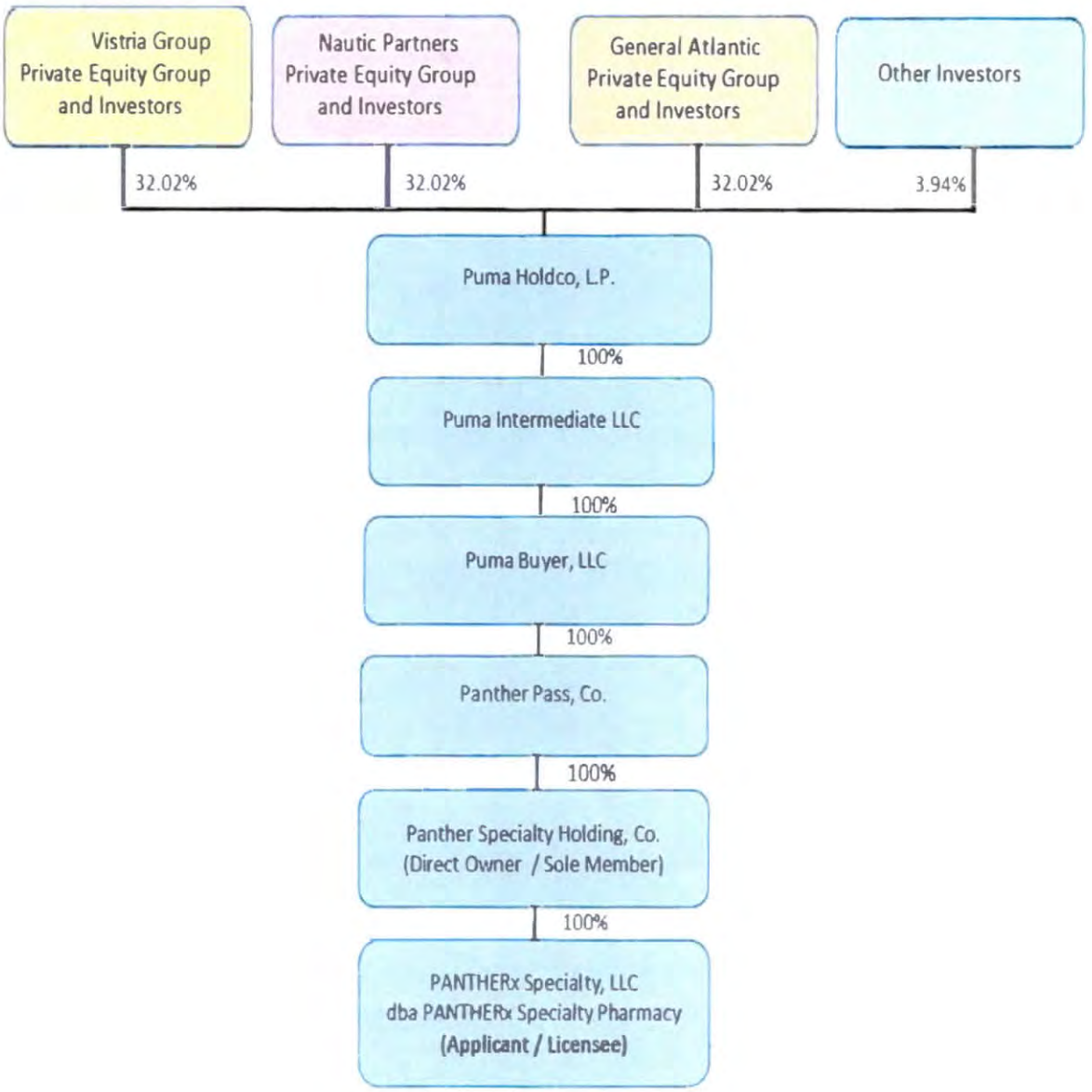
Ownership and Officers

Panther Specialty Holding Co. owns 100% of and is the parent company of PANTHERX Specialty LLC d/b/a Panther Specialty Pharmacy.

The officers of PANTHERX Specialty LLC d/b/a Panther Specialty Pharmacy are as follows:

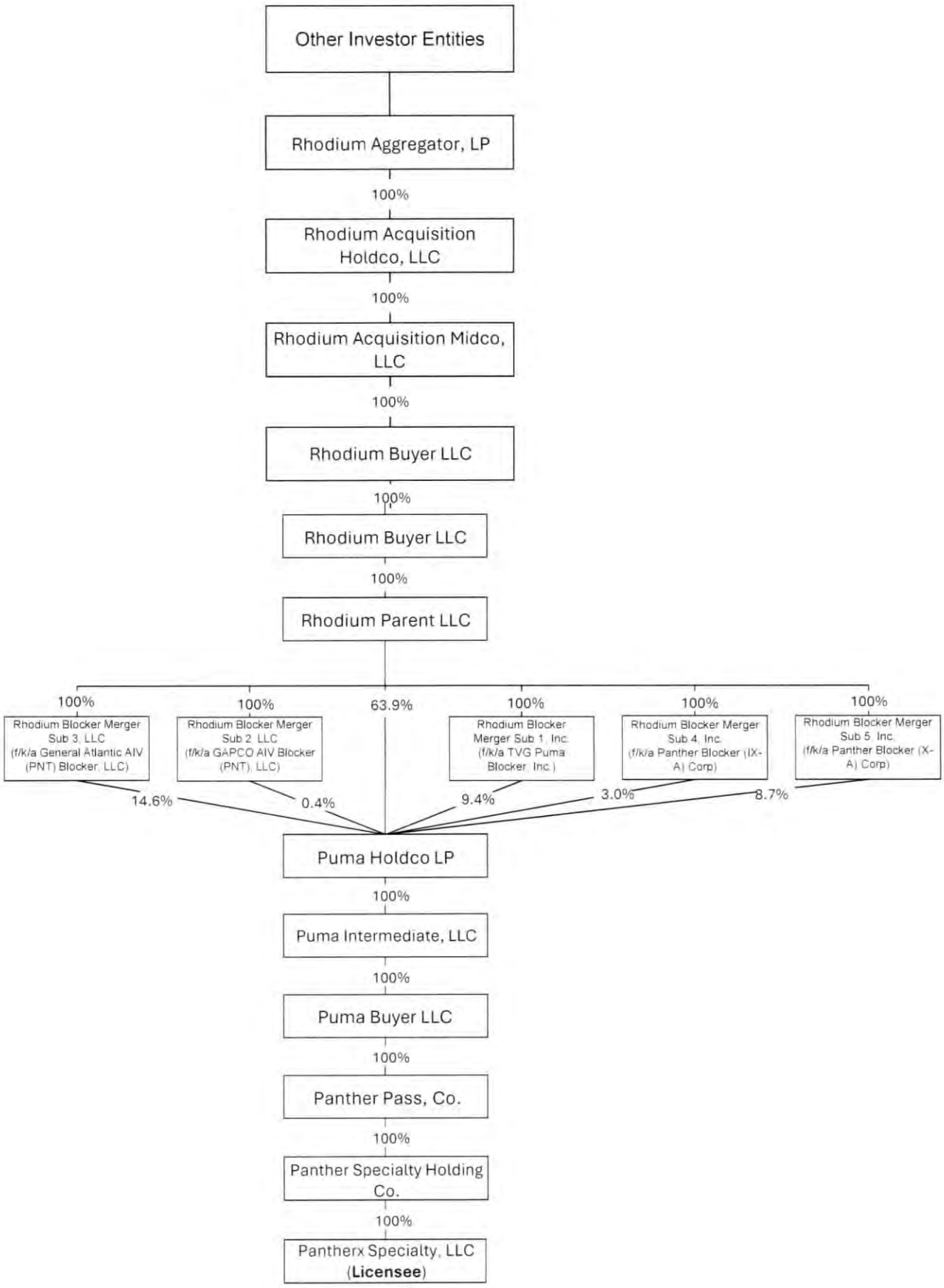
1. Bansi Nagji, Chief Executive Officer
2. Arik Moav, Chief Financial Officer
3. Robert Snyder, Executive Chair
4. Richard Faris, Chief Commercial and Clinical Officer

PANTHERx Specialty, LLC dba PANTHERx Specialty Pharmacy
Pre-Close Organizational Chart



Post-Closing Organisational Chart

CONFIDENTIAL



Pennsylvania Department of State

Bureau of Corporations and Charitable Organizations
PO Box 8722 | Harrisburg, PA 17105-8722
T:717-787-1057
dos.pa.gov/BusinessCharities

Regarding:	PANTHERx Specialty, LLC
Request Type:	Subsistence Certificate
Request No.:	084237629
Receipt No.:	003038053
Filing Type:	Domestic Limited Liability Company
Filing Subtype:	Limited Liability Company
Initial Filing Date:	October 14, 2011
Status:	Active

Issuance Date: July 25, 2026
File No.: 0004061605

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT

PANTHERx Specialty, LLC

is currently subsisting on the records of the Department of State as of the issuance date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.



IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the seal of my office to be affixed, the day and year above written

Albert Schmidt
Secretary of the Commonwealth

Verify this certificate online at www.file.dos.pa.gov

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler PANTHERx Specialty, LLC

Pharmacy/Wholesaler License # (if applicable) PH04087

Physical Address 1120 Stevenson Mill Rd, Ste 400

City Coraopolis State PA Zip 15108

Mailing Address (if different from physical address) 121 Bayer Rd, Building 5

City Pittsburgh State PA Zip 15205

Telephone 855-726-8479 Website www.pantherxrare.com

Licensing Company Email licensing@pantherxrare.com

Section 2: Personal Information

First Gregory Middle Allan Last Lucas

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City Carnegie State PA Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Duquesne University School of Pharmacy		08/05-05/11	
Address	**City**	**State**	**Zip**
600 Forbes Ave.	Pittsburgh	PA	15282
Diploma/Degree obtained, if any			
Doctor of Pharmacy (PharmD)			

School Name		From - To (MM/YY – MM/YY)	
Portage Area High School		08/01-06/05	
Address	**City**	**State**	**Zip**
85 Mountain Ave.	Portage	PA	15946
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/18-Current	[redacted]	Carnegie	PA	[redacted]
07/10-3/18	[redacted]	Pittsburgh	PA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
PANTHERx Specialty Pharmacy			12/21-Current
Business Address	**City**	**State**	**Zip**
1120 Stevenson Mill Rd. Suite 400	Coraopolis	PA	15108
Phone	**Title**		**Number of Employed Hours**
855-726-8479	Sr. Manager, Procurement and Dispensing Strategies		~9600
Description of Duties			
Manage fulfillment department activities (picking, packing, shipping), oversee management of inventory levels, on-board new manufacturer programs, review metrics and workflow, maintain compliance with state and federal regulations.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

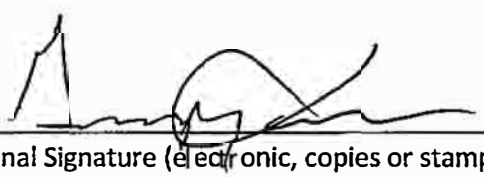
Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

9/3/26

Date

I, Gregory Lucas, **certify that as the designated representative for**

PANTHERx Specialty, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Gregory Lucas

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

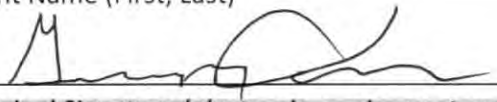
9/3/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gregory Lucas

Print Name (First, Last)



Original Signature (electronic, copies or stamps not accepted)

9/3/26

Date

Please have this section completed in the presence of a Notary Public.

Commonwealth
State of Pennsylvania, ss. County of Allegheny

I, Gregory Lucas, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.



Original Signature

9/3/26

Date

Subscribed and Sworn to before me this 3rd day of September, 2026.



Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Karen L. Randall, Notary Public
Allegheny County
My commission expires April 5, 2029
Commission number 1206384
Member, Pennsylvania Association of Notaries

(Seal)

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

PANTHERX SPECIALTY PHARMACY

1120 STEVENSON MILL ROAD
SUITE 400
CORAOPOLIS, PA, 15108

Phone:
Owner:

LICENSE

License No: AA0006068245 (PP482876)
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: New Business

Inspection Date: 04/17/2025
Inspection Result: Passed

Remarks:

The undersigned licensee, designee, or other authorized representative of the licensee acknowledges the completion of this inspection and the results as indicated on the summary and checklist reports.

If this is a New Business Inspection, this PASS inspection form will serve as a temporary authority to operate pending final review and approval by the State Board. The temporary authority must be prominently displayed and will expire upon receipt of a properly issued license or six months from the date of inspection.

CORY ULISSE	4/17/2025 11:55:52 AM	Gregory Allan Lucas - RP446181
Signature of Inspector	Date/Time	Signature of Owner/Representative

Confidentiality language:
Proprietary and Confidential -
Not a public record pursuant to
Section 7927.605 of the CPRA
and 45 CFR Section 5.31

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

PANTHERX SPECIALTY PHARMACY

1120 STEVENSON MILL ROAD
SUITE 400
CORAOPOLIS, PA, 15108

Phone:
Owner:

LICENSE

License No: AA0006068245 (PP482876)
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: New Business

Inspection Date: 04/17/2025
Inspection Result: Passed

Remarks:

Question	Answer
Are all licenses current and posted?	YES
Is a "No Smoking" sign prominently posted?	YES
Is the generic equivalent sign and list of commonly used equivalents properly posted?	YES
Is there a refrigerator with temperature monitoring for drug storage only?	YES
Is hot and cold water available in the prescription area?	YES
Are current copies of all Federal, State, and Board statues and regulations pertaining to pharmacy practice available? (Internet access is acceptable)	YES
Are outdated drugs appropriately removed from active stock?	YES
Does the pharmacy meet all security requirements?	YES
Does the pharmacy have adequate equipment and supplies to enable it to properly prepare and dispense consistent with the pharmacy's scope of practice?	YES
Is the pharmacy in compliance with all sanitation, cleanliness, maintenance, and construction requirements?	YES
Do labels have all the required information and match the license record?	YES
Are all prescriptions verified by registered pharmacists?	YES
Is the name or initials of the dispensing pharmacist noted on the prescriptions?	YES
Are prescription files properly maintained? (electronic files are acceptable)	YES
Are transferred prescriptions properly recorded?	YES
Are Schedule II drugs securely locked in a substantially constructed cabinet or dispersed throughout the stock?	YES
Are there signed and dated protocols for each pharmacy technician?	YES
Does the pharmacy have an automated medication system?	NO
Does the pharmacy administer injectable medications, biologicals, or immunizations?	NO

Confidentiality language:
Proprietary and Confidential -
Not a public record pursuant to
Section 7927.605 of the CPRA
and 45 CFR Section 5.31

Commonwealth of Pennsylvania- Department of State
Bureau of Professional and Occupational Affairs

Mailing Address P.O. Box 2649, Harrisburg, PA 17105 Toll Free: 1-833-DOS-BPOA

PANTHERX SPECIALTY PHARMACY
GREGORY ALLAN LUCAS

License Number	: PP482876	Initial License Date : 04/02/2019	Expiration Date	: 08/31/2027
License Type	: Pharmacy		License Status as of 7/10/2025	: Active
Issued By	: State Board of Pharmacy			
Address	: 1120 STEVENSON MILL ROAD, SUITE 400 CORAOPOLIS, PA 15108			

COMMONWEALTH OF PENNSYLVANIA • DEPARTMENT OF STATE

Arion R. Claggett

Acting Commissioner Arion R. Claggett

Signature of Licensee

SCAN ME

Please verify the license by visiting https://www.pals.pa.gov/verify or by scanning the QR Code

202507091220

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
POST OFFICE BOX 2649
HARRISBURG, PA 17105-2649

www.dos.pa.gov

09/09/2026

Verification/Certification of License

This is to certify that the individual or business named below is licensed by the Department of State, Bureau of Professional and Occupational Affairs:

NAME:	PANTHERX SPECIALTY PHARMACY
LICENSE TYPE:	Pharmacy
LICENSE #:	PP482876
LICENSE STATUS:	Active
LICENSE ISSUE DATE:	04/02/2019
LICENSE EXPIRATION DATE:	08/31/2027
DISCIPLINARY HISTORY:	No Disciplinary Action Exists

Arion R. Claggett

Acting Commissioner Arion R. Claggett
Bureau of Professional and Occupational Affairs



BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

P. O. Box 2649

Harrisburg, PA 17105-2649

09/16/2026

License Information

PANTHERX SPECIALTY PHARMACY

1120 STEVENSON MILL ROAD SUITE 400
CORAOPOLIS, Pennsylvania 15108

Board/Commission:	State Board of Pharmacy	Status Effective Date:	04/02/2019
LicenseType:	Pharmacy	Issue Date:	04/02/2019
Specialty Type:		Expiration Date:	08/31/2027
License Number:	PP482876	Last Renewal:	07/09/2025
Status:	Active		

Prerequisite Information

Licensee	Relationship	License Type	License Number	License Status	Associated Date	License Expiration Date
GREGORY ALLAN LUCAS	Pharmacist Manager	Pharmacist	RP446181	Active	01/15/2024	09/30/2028

Disciplinary Action Details

No disciplinary actions were found for this license.

This site is considered a primary source for verification of license credentials provided by the Pennsylvania Department of State.

4TT

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada	☐ New Pharmacy ☑ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH 03223	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☑ Other: Specialty mail-order.	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Pantherx Specialty Pharmacy

Physical Address: 24 Summit Park Drive Suite 101

City: Pittsburgh State: PA Zip: 15275

Mailing Address (if different from physical address): N/A

City: _____ State: _____ Zip: _____

Telephone: (855) 726-8479 Toll Free # (NAC 639.708, NRS 639.23286): (855) 726-8479

Fax: (855) 246-3986 Contact Email: licensing@pantherxrare.com

Website: www.pantherxrare.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Dina DelPizzo Mawhinney

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): N/A

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Andrew McIlvaine	NV Pharmacist Registration #: 22502
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Pennsylvania

Parent Company (if any): Panther Specialty Holding Co.

Corporation/Organization Name: PANTHERx Specialty, LLC

Mailing Address: 24 Summit Park Drive, Suite 101

City: Pittsburgh State: PA Zip: 15275

Telephone: (855) 726-8479 Email: licensing@pantherxrare.com

Contact Person Name: Dina DelPizzo Mawhinney

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist-in-Charge (title) for PANTHERx Specialty, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Dina DelPizzo Mawhinney

Print Name of Authorized Person

Dina DelPizzo Mawhinney

Original signature of Authorized Person (copies or stamps not accepted)

9/8/2026

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Dina DelPizzo Mawhinney hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist-in-Charge (title) for PANTHERx Specialty, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Dina DelPizzo Mawhinney

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 8th day of September, 20 26

Karen L Randall

Notary Public

Commonwealth of Pennsylvania - Notary Seal
Karen L. Randall, Notary Public
Allegheny County
My commission expires April 5, 2029
Commission number 1206384
Member, Pennsylvania Association of Notaries

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Snyder, Executive Chair

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

9/4/2026

Date

Board Use Only	Date Received: 9/14/26	Amount: 500.00/V# 574886

Pantherx Specialty Pharmacy

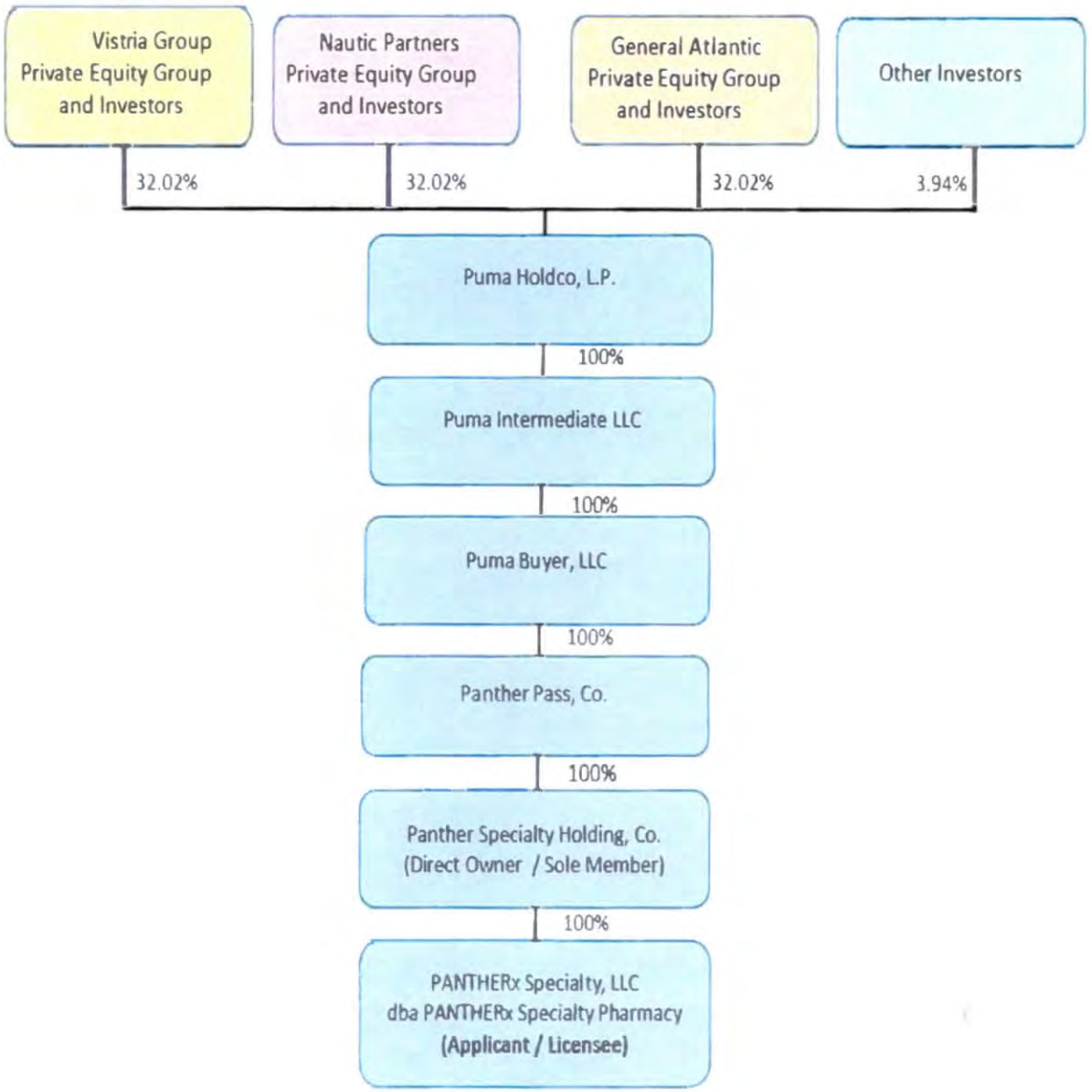
Ownership and Officers

Panther Specialty Holding Co. owns 100% of and is the parent company of PANTHERX Specialty LLC d/b/a Panther Specialty Pharmacy.

The officers of PANTHERX Specialty LLC d/b/a Panther Specialty Pharmacy are as follows:

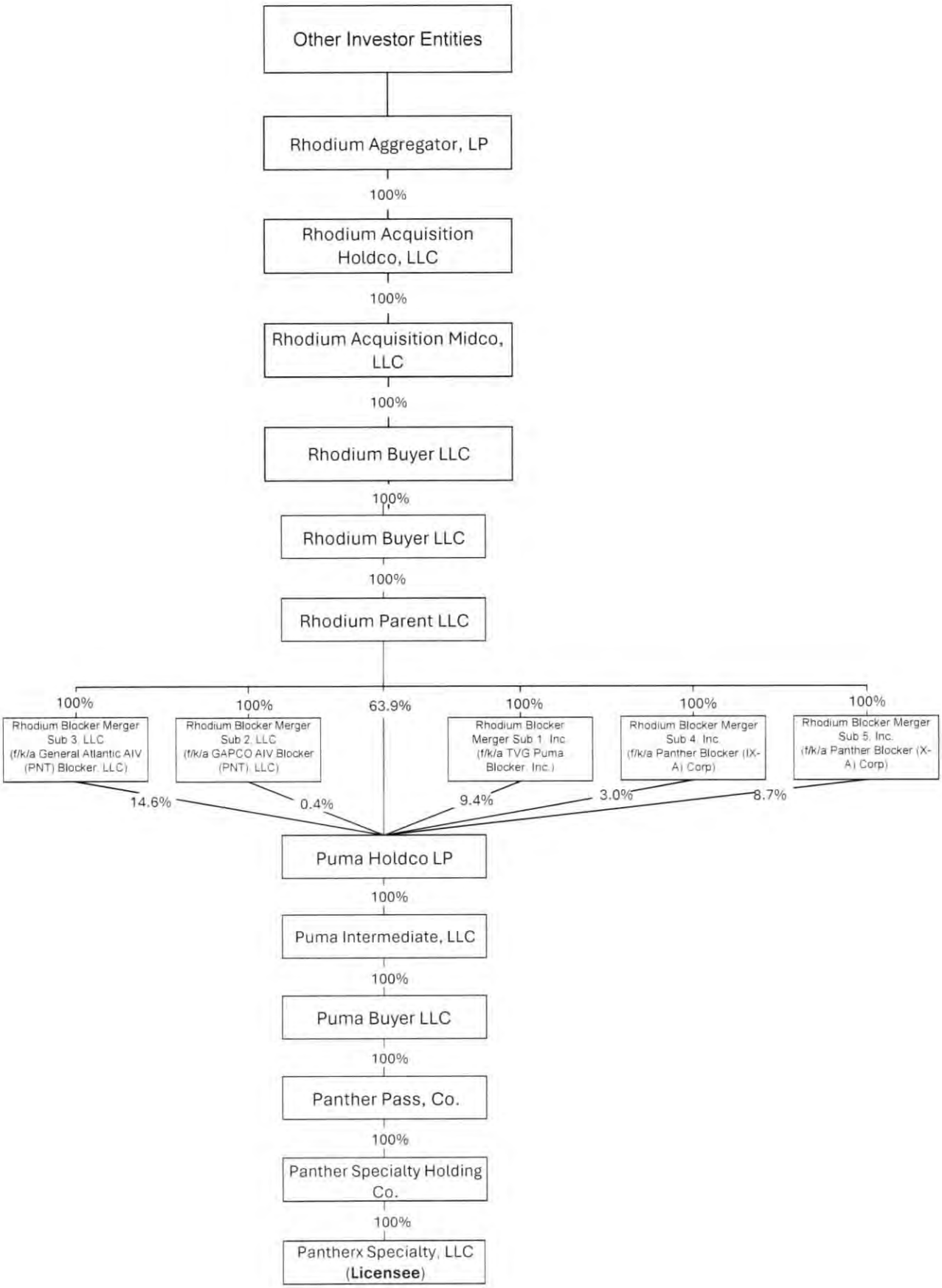
1. Bansi Nagji, Chief Executive Officer
2. Arik Moav, Chief Financial Officer
3. Robert Snyder, Executive Chair
4. Richard Faris, Chief Commercial and Clinical Officer

PANTHERx Specialty, LLC dba PANTHERx Specialty Pharmacy
Pre-Close Organizational Chart



Post-Closing Organisational Chart

CONFIDENTIAL



Pennsylvania Department of State

Bureau of Corporations and Charitable Organizations
PO Box 8722 | Harrisburg, PA 17105-8722
T:717-787-1057
dos.pa.gov/BusinessCharities

Regarding:	PANTHERx Specialty, LLC
Request Type:	Subsistence Certificate
Request No.:	084237629
Receipt No.:	003038053
Filing Type:	Domestic Limited Liability Company
Filing Subtype:	Limited Liability Company
Initial Filing Date:	October 14, 2011
Status:	Active

Issuance Date: July 25, 2026
File No.: 0004061605

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT

PANTHERx Specialty, LLC

is currently subsisting on the records of the Department of State as of the issuance date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.

COMMONWEALTH OF PENNSYLVANIA • DEPARTMENT OF STATE •

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the seal of my office to be affixed, the day and year above written

Albert Schmidt
Secretary of the Commonwealth

Verify this certificate online at www.file.dos.pa.gov

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler PANTHERx Specialty, LLC
Pharmacy/Wholesaler License # (if applicable) PH03223
Physical Address 24 Summit Park Dr, Ste 101
City Pittsburgh State PA Zip 15275
Mailing Address (if different from physical address) 121 Bayer Rd, Building 5
City Pittsburgh State PA Zip 15205
Telephone 855-726-8479 Website www.pantherxrare.com
Licensing Company Email licensing@pantherxrare.com

Section 2: Personal Information

First Dina Middle Marie Last DelPizzo Mawhinney
Alias(es, nicknames, name changes, etc.)
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X
Mailing Address [redacted]
City Oakdale State PA Zip [redacted]
Telephone [redacted] Email [redacted]
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		n/a

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Duquesne University		From - To (MM/YY – MM/YY): 8/2002 – 5/2008	
Address: 600 Forbes Ave	City: Pgh	State: PA	Zip: 15282
Diploma/Degree obtained, if any: Pharm D			
School Name: Shaler Area High School		From - To (MM/YY – MM/YY): 8/98 – 6/2002	
Address: 381 Wible Run Rd.	City: Pgh	State: PA	Zip: 15209
Diploma/Degree obtained, if any: High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): 4/23 – Present	[redacted]	City: Oakdale	State: PA	[redacted]
From - To (MM/YY – MM/YY): 8/21 – 4/23		City: Cranberry Twp	State: PA	
From - To (MM/YY – MM/YY): 1/17 – 8/21		City: Pgh	State: PA	
From - To (MM/YY – MM/YY): 7/02 – 1/17		City: Pgh	State: PA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
PANTHERx SPECIALTY Pharmacy			12/19 – Present	
Business Address		City	State	Zip
245 Summit Park Drive Ste 101		Pgh	PA	15275
Phone	Title		Number of Employed Hours	
855-726-8479	Sr. Director, Fulfillment Services		1413 hours	
Description of Duties				
Manage/Oversee fulfillment, inventory, shipping & warehouse dept. maintain compliance with state & federal regulations				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		n/a
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

9/8/26
Date

I, Dina DelPizzo Mawhinney, **certify that as the designated representative for**

PANTHERx Specialty, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DMM I am at least 21 years of age;
3. DMM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DMM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DMM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DMM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DMM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Dina DelPizzo Mawhinney

Print Name (First, Last)

Dina DelPizzo Mawhinney

Original Signature (electronic, copies or stamps not accepted)

9/8/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dina DelPizzo Mawhinney

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) — Date: 9/18/26

Please have this section completed in the presence of a Notary Public.

Commonwealth ~~State~~ of Pennsylvania, ss. County of Allegheny

I, Dina DelPizzo Mawhinney, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature — **Date:** 9/18/26

Subscribed and Sworn to before me this 8th day of September, 2026

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Karen L. Randall, Notary Public
Allegheny County
My commission expires April 5, 2029
Commission number 1206384
Member, Pennsylvania Association of Notaries

(Seal)

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 833-367-2762 Fax: 717-787-7769

FACILITY

PANTHERX SPECIALTY PHARMACY

24 SUMMIT PARK DR STE 101
Pittsburgh, Pennsylvania, 15275

Phone: 412-246-9858
Owner: PANTHERX SPECIALTY, LLC

LICENSE

License No: PP482247
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: Non-Directed Routine

Inspection Date: 10/07/2025
Inspection Result: Passed

Remarks:

Question	Answer
Are all licenses current and posted?	YES
Is a "No Smoking" sign prominently posted?	YES
Is the generic equivalent sign and list of commonly used equivalents properly posted?	YES
Is there a refrigerator with temperature monitoring for drug storage only?	YES
Is hot and cold water available in the prescription area?	YES
Are current copies of all Federal, State, and Board statues and regulations pertaining to pharmacy practice available? (Internet access is acceptable)	YES
Are outdated drugs appropriately removed from active stock?	YES
Does the pharmacy meet all security requirements?	YES
Does the pharmacy have adequate equipment and supplies to enable it to properly prepare and dispense consistent with the pharmacy's scope of practice?	YES
Is the pharmacy in compliance with all sanitation, cleanliness, maintenance, and construction requirements?	YES
Do labels have all the required information and match the license record?	YES
Are all prescriptions verified by registered pharmacists?	YES
Is the name or initials of the dispensing pharmacist noted on the prescriptions?	YES
Are prescription files properly maintained? (electronic files are acceptable)	YES
Are transferred prescriptions properly recorded?	YES
Are Schedule II drugs securely locked in a substantially constructed cabinet or dispersed throughout the stock?	YES
Are there signed and dated protocols for each pharmacy technician?	YES
Does the pharmacy have an automated medication system?	NO
Does the pharmacy administer injectable medications, biologicals, or immunizations?	NO

Proprietary and Confidential - Not a public record pursuant to Section 7927.605 of the CPRA and 45 CFR Section 5.31

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 833-367-2762 Fax: 717-787-7769

FACILITY

PANTHERX SPECIALTY PHARMACY

24 SUMMIT PARK DR STE 101
Pittsburgh, Pennsylvania, 15275

Phone: 412-246-9858
Owner: PANTHERX SPECIALTY, LLC

LICENSE

License No: PP482247
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: Non-Directed Routine

Inspection Date: 10/07/2025
Inspection Result: Passed

Remarks:

The undersigned licensee, designee, or other authorized representative of the licensee acknowledges the completion of this inspection and the results as indicated on the summary and checklist reports.

CORY ULISSE	10/7/2025 11:27:24 AM	Dina Marie DelPizzo Mawhinney - RP443006
Signature of Inspector	Date/Time	Signature of Owner/Representative

Proprietary and Confidential - Not a public record pursuant to Section 7927.605 of the CPRA and 45 CFR Section 5.31

Commonwealth of Pennsylvania- Department of State
Bureau of Professional and Occupational Affairs

Mailing Address P.O. Box 2649, Harrisburg, PA 17105 Toll Free: 1-833-DOS-BPOA

PANTHERX SPECIALTY PHARMACY
DINA MARIE DELPIZZO MAWHINNEY

License Number	: PP482247	Initial License Date : 04/02/2012	Expiration Date	: 08/31/2027
License Type	: Pharmacy		License Status as of 7/10/2025	: Active
Issued By	: State Board of Pharmacy			
Address	: 24 SUMMIT PARK DR STE 101, Pittsburgh, PA 15275			

COMMONWEALTH OF PENNSYLVANIA • DEPARTMENT OF STATE

Arion R. Claggett

Acting Commissioner Arion R. Claggett

Signature of Licensee

SCAN ME

Please verify the license by visiting https://www.pals.pa.gov/verify or by scanning the QR Code

202507091215



BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

P. O. Box 2649

Harrisburg, PA 17105-2649

09/16/2026

License Information

PANTHERX SPECIALTY PHARMACY

24 SUMMIT PARK DR STE 101
Pittsburgh, Pennsylvania 15275

Board/Commission:	State Board of Pharmacy	Status Effective Date:	05/05/2015
LicenseType:	Pharmacy	Issue Date:	04/02/2012
Specialty Type:	Inspected by Board	Expiration Date:	08/31/2027
License Number:	PP482247	Last Renewal:	07/09/2025
Status:	Active		

Prerequisite Information

Licensee	Relationship	License Type	License Number	License Status	Associated Date	License Expiration Date
DINA MARIE DELPIZZO MAWHINNEY	Pharmacist Manager	Pharmacist	RP443006	Active	01/15/2024	09/30/2028

Disciplinary Action Details

No disciplinary actions were found for this license.

This site is considered a primary source for verification of license credentials provided by the Pennsylvania Department of State.

4UU

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: [redacted]
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Walgreens Specialty Pharmacy #15987

Physical Address: 1020 29th St, Suite 140

City: Sacramento State: CA Zip: 95816

Mailing Address (if different from physical address): PO Box 901

City: Deerfield State: IL Zip: 60015

Telephone: 916 738 3300 Toll Free # (NAC 639.708, NRS 639.23286): 888-750-3026

Fax: 916 738 3302 Contact Email: specialtylicenses@walgreens.com

Website: www.walgreens.com

Nevada Business License # (if applicable) NV19951143510

Supervising/Managing Pharmacist Name (NRS 639.220): Denny Biju

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): N/A

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Megan Patterson	NV Pharmacist Registration #: 25283
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NR5.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Illinois

Parent Company (if any): Walgreens Holding Company

Corporation/Organization Name: Walgreen Co.

Mailing Address: 108 Wilmot Road

City: Deerfield State: IL Zip: 60015

Telephone: 847 224 1348 Email: licenseadministration@walgreens.com

Contact Person Name: Kayla Lechner

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Licensing and Provider Enroll (title) for Walgreens Specialty Pharmacy #15987 (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Michael Handal

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

8/20/2026

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Michael Handal hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Licensing and Provider Enrollment (title) for Walgreens Specialty Pharmacy #15987 (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 20th day of August, 2026

Notary Public

OFFICIAL SEAL
CHERYL R BROOKS
Commission No. 1034902
NOTARY PUBLIC, STATE OF ILLINOIS
My Commission Expires 07/13/2030

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Handal

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

8/20/2026

Date

Board Use Only	Date Received: 8/31/26	Amount: $500 - Ch 1000030114

CONFIDENTIAL/EXEMPT FROM FREEDOM OF INFORMATION ACT AND SIMILAR STATE REQUESTS

Ownership Information

Ownership & Leadership of Applicant Entity

Applicant: **Walgreen Co.**
108 Wilmot Rd., Deerfield, IL 60015

Ownership: The Applicant entity is wholly owned (100%) by Walgreens Holding Company

Officers of Walgreen Co.
Michael Motz - CEO
Richard Gates - Senior Vice President and Chief Pharmacy Officer
Paul Lim - Secretary
Michael Handal - Licensing and Provider Enrollment Officer

Ownership & Leadership of Walgreens Boots Alliance, Inc.

Ownership: Walgreens Holding Company is wholly owned (100%) by Blazing Star Parent, LLC

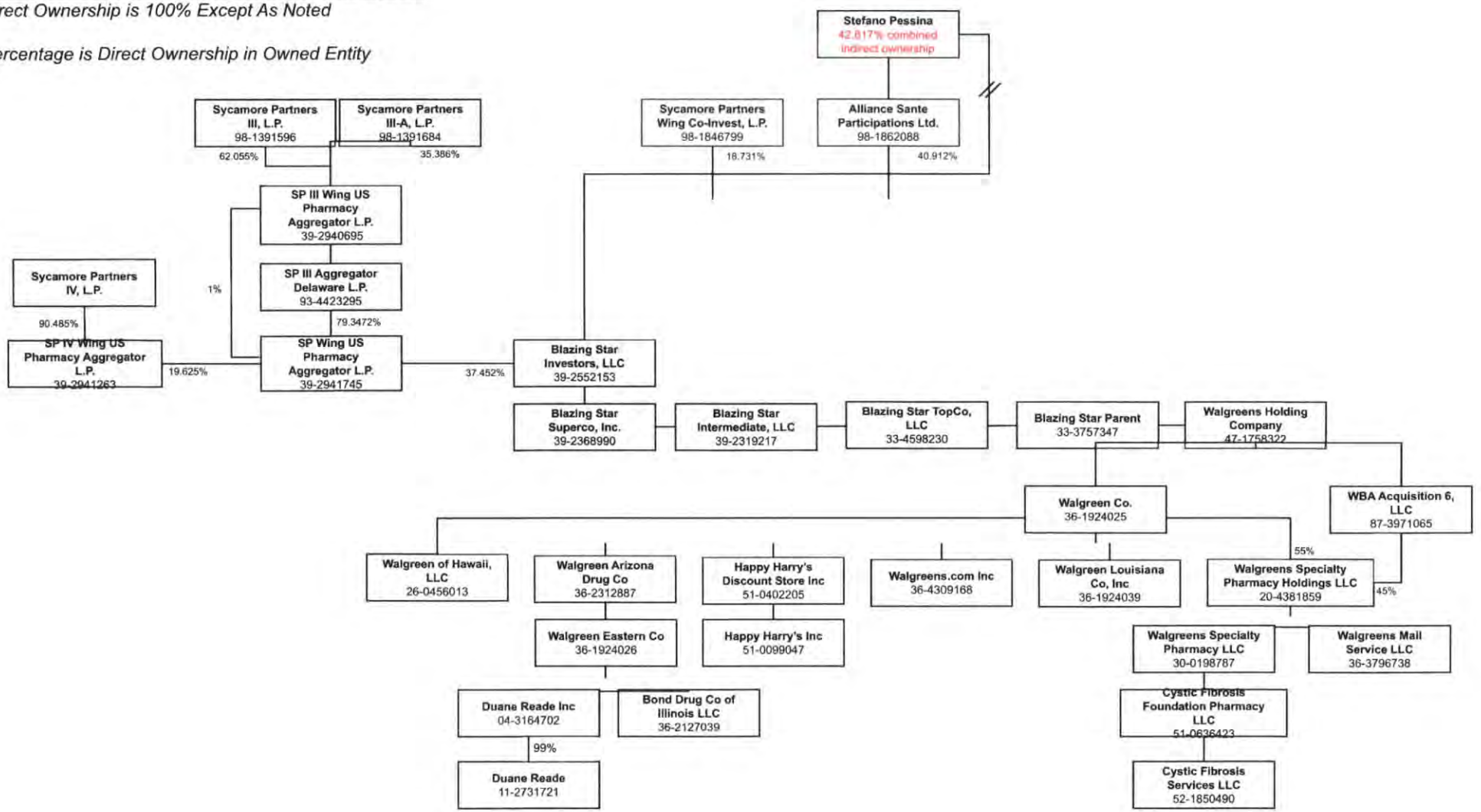
Officers of Walgreens Holding Company
Michael Motz - CEO
Jeff Hall - COO
Mark Weisz - Sr VP, Global Tax
J. Brandon Neal - Corporate Secretary

Please see the attached Corporate Organization chart for reference.

Post-Restructuring Organizational Chart

Direct Ownership is 100% Except As Noted

Percentage is Direct Ownership in Owned Entity



Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	WALGREEN CO.
Entity No.:	0365922
Registration Date:	12/29/1958
Entity Type:	Stock Corporation - Out of State - Stock
Formed In:	ILLINOIS
Status:	Active

The above referenced entity is active on the Secretary of State's records and is qualified to transact intrastate business in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of August 03, 2026.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 486969748

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Walgreens Specialty Pharmacy #15987

Pharmacy/Wholesaler License # (if applicable): _____

Physical Address: 1020 29th St, Suite 140

City: Sacramento State: CA Zip: 95816

Mailing Address (If different from physical address): PO Box 901

City: Deerfield State: IL Zip: 60015

Telephone: 916-738-3300 Website: www.walgreens.com

Licensing Company Email: specialtylicenses@walgreens.com

Section 2: Personal Information

First: Megan Middle: ~~Elizabeth~~ Jackson Last: Patterson

Alias(es, nicknames, name changes, etc.): Megan Elizabeth Jackson (maiden name)

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: West Sacramento State: CA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: South Carolina College of Pharmacy			From - To (MM/YY – MM/YY): 08/13 – 05/17	
Address: 715 Sumter St	City: Columbia		State: SC	Zip: 29208
Diploma/Degree obtained, if any: PharmD				
School Name: University of South Carolina – Columbia			From - To (MM/YY – MM/YY): 08/11 – 05/13	
Address: 1501 Pendleton St.	City: Columbia		State: SC	Zip: 29208
Diploma/Degree obtained, if any: Undergraduate pre-reqs for pharmacy school				
School Name: Hopewell High School			From - To (MM/YY – MM/YY): 08/07 – 05/11	
Address: 11530 Beatties Ford Rd	City: Huntersville		State: NC	Zip: 28078
Diploma/Degree obtained, if any: High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/23 – present	[redacted]	West Sacramento	CA	[redacted]
07/22 – 10/23	[redacted]	West Sacramento	CA	[redacted]
07/20 – 07/22	[redacted]	Tucson	AZ	[redacted]
07/18 – 07/20	[redacted]	Chicago	IL	[redacted]
06/17 – 07/18	[redacted]	Columbia	SC	[redacted]
06/15 – 06/17	[redacted]	Columbia	SC	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Walgreens Specialty				From - To (MM/YY – MM/YY): 06/24 - present
Business Address: 1020 29th St, Ste 140	City: Sacramento		State: CA	Zip: 95816
Phone: 916-738-3300	Title: Site/Pharmacy Manager		Number of Employed Hours: 5760	
Description of Duties: manage technicians/pharmacists, maintain compliance, grow business				

Business Name: Walgreens				From - To (MM/YY – MM/YY): 08/22 - 06/24
Business Address: 1401 Broadway	City: Sacramento		State: CA	Zip: 95818
Phone: 916-440-0953	Title: Pharmacy Manager		Number of Employed Hours: 2560	
Description of Duties: manage technicians/pharmacists, maintain compliance				

Business Name: Walgreens				From - To (MM/YY – MM/YY): 07/20 - 07/22
Business Address: 12965 N Oracle Rd	City: Oro Valley		State: AZ	Zip: 85739
Phone: 520-825-7747	Title: Pharmacy Manager		Number of Employed Hours: 4160	
Description of Duties: manage technicians/pharmacists, maintain compliance				

Business Name: Walgreens				From - To (MM/YY – MM/YY): 08/18 - 07/20
Business Address: 3046 N Halsted St.	City: Chicago		State: IL	Zip: 60657
Phone: 773-325-0413	Title: Pharmacy Manager		Number of Employed Hours: 3360	
Description of Duties: manage technicians/pharmacists, maintain compliance				

Business Name: CVS				From - To (MM/YY – MM/YY): 07/17 - 07/18
Business Address: 7749 Garners Ferry Rd	City: Columbia		State: SC	Zip: 29209
Phone: 803-776-6605	Title: Staff Pharmacist		Number of Employed Hours: 2080	
Description of Duties: assist pharmacy manager in managing team/daily workflow & maintain compliance				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
CVS			10/14 - 07/17
Business Address	**City**	**State**	**Zip**
900 Assembly St	Columbia	SC	29201
Phone	**Title**	**Number of Employed Hours**	
803-212-7016	Intern	3120 (intern)	
Description of Duties			
assist pharmacists with workflow, gain pharmacy/medication knowledge			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Megan Patterson, **certify that as the designated representative for**

Walgreens Specialty Pharmacy #15987,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MP I am at least 21 years of age;
3. MP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Megan Patterson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09/05/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Megan Patterson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/5/2026

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Sacramento

I, Megan Patterson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/5/26

Date

Subscribed and Sworn to before me this 5 day of Sept, 2026

Notary Public Signature

MEGHAN C. DEAL
COMM. # 2540875
NOTARY PUBLIC • CALIFORNIA
SACRAMENTO COUNTY
Comm. Expires MAR. 24, 2030

(Seal)

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 3/18/2024 Inspector: Steven Kyle

Firm: WALGREENS PHARMACY #15987 Phone: (916) 733-3000

Address: 1020 29TH ST STE 140 City: SACRAMENTO Zip: 95816

Ownership: CORPORATION

Permit #: PHY53325 Permit Exp: 12/1/2024 DEA#: [redacted] DEA Exp: 5/31/2025

Date of Self Assessment Form: 7/26/2023 Other Permit #: N/A Date of DEA Inventory: 6/9/2023

Hours M-F: 8AM-5:30PM Hours Saturday CLOSED Hours Sunday: CLOSED

PIC BRANDY W SANCHEZ RPH84400 Administrator

RPH Consultant

Staff RPH Name:	License #:	Staff Name:	License #:
ISAIAH S SAYABATH	INT46677	DAVID LY	TCH64154
MEGAN J PATTERSON	RPH86184	DELILAH N MARTINEZ	TCH193584
MANJINDER K GILL	RPH69896	DEPINDER K KHERA	TCH180224
SYLVIA V SWEET	RPH68249	HUONG T LY	TCH77746
HADEEL S JAHAMI	RPH87501	LUCIANA MIRANDOLA	TCH47220
CHRIS KOSHY NEBU	RPH88422	MARGEE MAE C DELA CRUZ	TCH163288
DENNY C BIJU	RPH87616	SARAH N LAWYER	TCH109778
		SUSAN D VAN	TCH71630

Inspector Remarks:

Routine Pharmacy Inspection
Specialty pharmacy, mainly transplant, oncology, auto-immune
Most prescriptions are mailed, occasional pickup
Currently licensed in CA only, no out of state dispensing
Located within medical office building, adjacent to Sutter Hospital
RX Volume approx. 150 prescriptions/day
Provides immunization – <1/day
Non-sterile non-hazardous compounding – approx. 1-2 compounds/week

Reviewed:
Pharmacy Permit and renewal
DEA registration
Biennial Controlled Substances Inventory
Self-Assessment
Compounding self-assessment, NA, no compounding

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Notice to Consumer Poster
Language notice/interpretive service
POA
Outdates quarantined
Consultation
Premise condition
Refrigerator temperature, monitored
Freezer temperature, monitored
Sink with hot and cold water
Security: Surveillance cameras, restricted entry
CII security, locked safe
CII orders: CSOS
Recent CII invoices
CII and CIII-V prescriptions
CII Rx and invoices filed separately
CURES reporting for last quarter
CURES access for all pharmacists
Licensees required to subscribe to Board emails: https://pharmacy.ca.gov/webapplications/apps/subscribe/index.shtml
DEA 106
Prescription filling and verification process
Will call prescriptions
Controlled substance reconciliation

Policies and Procedures required:
Quality Assurance Policy and Incident Reports
Impaired employee/Theft and diversion
Technician Job Description
Temporary absence of Pharmacist
Interpretive service
Immunization

Discussion:
1. Pharmacy permit and renewal must be posted in clear public view
2. Misbranding based on expiration date, especially RTS labels
3. Biennial controlled substance inventory requirements
4. Technician to pharmacist ratio requirements, based on duties
5. Compounding requirements
6. QA reports per CCR 1711
7. Labeling requirements for generic drugs per CCR 1707.5

Steven Kyle, PharmD
Pharmacy Inspector
CA Board of Pharmacy

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: 916-472-1036
Email: steven.kyle@dca.ca.gov

Ask an Inspector Program

The board can be contacted with questions pertaining to pharmacy law and regulations.

- *Email: ask.inspector@dca.ca.gov: Include name, organization, phone, and best call time*
- *Fax: (916) 574-8618*
- *Phone: (916) 518-3100 (Monday through Thursday from 9 a.m. to 1 p.m.)*

Board of Pharmacy References

- **Visit the Board's website for valuable information:** www.pharmacy.ca.gov
- **The Script newsletter:** https://www.pharmacy.ca.gov/publications/script.shtml
- **Statutory Changes in Pharmacy Law:** https://www.pharmacy.ca.gov/laws_regs/new_laws.pdf
- **Frequently Asked Questions:** https://www.pharmacy.ca.gov/licensees/faqs.shtml

Educational topics

1. BPC 4052.04 – Pharmacist may furnish COVID-19 oral therapeutics following a positive test.
   - "COVID-19 oral therapeutics" means drugs that are approved or authorized by the FDA for the treatment of COVID-19 and administered orally.
   - Prior to furnishing COVID-19 oral therapeutics, a pharmacist shall utilize relevant and appropriate evidence-based clinical guidelines published by FDA in providing these patient care services.
   - A pharmacist who furnishes COVID-19 oral therapeutics shall notify patient's PCP or enter appropriate information into patient record system shared with PCP, as permitted by that PCP. If the patient does not have a PCP, the pharmacist shall provide the patient with a written record of the drugs furnished and advise the patient to consult a physician of the patient's choice.
   - Document the kind and amounts of COVID-19 oral therapeutics furnished, as well as any information regarding testing services provided, in the patient's record in the record system maintained by the pharmacy.
   - Retain records for 3 years.
2. BPC 4113 – PIC authority to make staffing decisions
   - PIC may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely.
   - If PIC is not available, a pharmacist on duty may adjust staffing according to workload if needed.
   - PIC or pharmacist on duty shall immediately notify the store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. If the conditions are not resolved within 24 hours, the PIC or RPH on duty shall ensure the BOP is timely notified. Conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff include, but are not limited to:

INSPECTION REPORT

- Workplace safety and health hazards that present an immediate risk of death, illness or irreparable harm to patients, personnel, or pharmacy staff.
- Sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions.
- Vermin infestation that poses a risk to the safety or efficacy of medicine.

3. BPC 4113.1 – Reporting medication errors within 14 days from discovery.
   - Applies to "community pharmacies" – *i.e.,* any pharmacy that dispenses medication to an outpatient (but not including facilities of CDCR).
   - Per the BOP's AB 1286 Implementation Statement, the reporting of medication errors under BPC 4113.1 will not be required until the BOP approves an entity to receive the reports.
4. BPC 4113.6 – Chain community pharmacy subject to BPC 4113.5 must be staffed at all times with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services. The BOP will not take action against a pharmacy for violation of this staffing requirement if any of the following conditions apply:
   - RPH on duty waives the requirement in writing during specified hours based on workload need.
   - The pharmacy is open beyond normal business hours (*i.e.,* before 8am, after 7pm). During the hours before 8am and after 7pm, the staffing requirement shall not apply.
   - The pharmacy's prescription volume per day on average is less than 75 prescriptions per day based on the average daily prescription volume for the past calendar year. However, if the pharmacist is also expected to provide additional pharmacy services (such as immunizations or CLIA-waived tests) this exception does not apply.

   When staffing of pharmacist hours within a chain community pharmacy does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted, and included on the outgoing telephone message.
5. BPC 4115 – Pharmacy technician may, under the direct supervision and control of a pharmacy, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are CLIA waived, receive prescription transfers, and accept clarification on prescriptions under certain specified conditions.
6. BPC 4231 – CE required for pharmacists to renew their pharmacist license must now include at least one hour of participation in a cultural competency course which meets specified requirements.

Compounding Information

November 1, 2023, is the compendial date for several USP General Chapters, including General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations, <797> Pharmaceutical Compounding—Sterile Preparations, <800> Hazardous Drugs—Handling in Healthcare Settings, and <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging. Consistent with the policy statement the Board released on September 12, 2023, it is the Board's expectation that licensees are moving forward with all necessary implementation activities to comply with the updated USP compounding standards.

The Board has undertaken a review of its compounding regulations and identified changes necessary to clarify or make more specific requirements of federal law and USP General Chapters.

During this transition period, licensees are encouraged to monitor the regulation process for updates, including signing up for the Board's subscriber alert system and by checking the Board's website.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Licensees are reminded to also ensure continuing compliance with other laws, regulations, and requirements that may apply to their activities, including, without limitation: the Federal Food, Drug, and Cosmetic Act (21 USC §§ 321–399i), including Section 503A thereof (21 USC § 353a); provisions of California's Sherman Food, Drug, and Cosmetic Law (Health and Safety Code §§ 109875–111929.4); and laws, regulations, and requirements related to radiopharmaceuticals and/or the handling of hazardous drugs, including requirements established by Cal/OSHA.

Educational Links and References:
1. Revisions to USP Compounding General Chapters <795> and <797> https://go.usp.org/2022_Revisions_795_797
   BUD Scientific Rationale for the 2021 Proposed Revisions to <795>
   BUD Reference for the 2021 Proposed Revisions to <795>
   BUD Scientific Rationale for the 2021 Proposed Revisions to <797>
   BUD Reference for the 2021 Proposed Revisions to <797>
2. 9/29/23, Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act.
   https://www.fda.gov/media/94155/download
3. FDA Drug Establishments Current Registration Site:
https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm
4. FDA to Compounders: Know Your Bulks and Excipients Suppliers:
   https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipients-suppliers

Disclaimer:
Any issues referenced/discussed in this report are not intended to be an all-inclusive list of issues that may exist at your facility. Your facility is responsible for investigating and determining the causes of any issues and items to be corrected and for preventing their recurrence. Further review of items provided at inspection, may result in further communication after this report.

Licensee Remarks:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) B W Sanchez

Pharmacist (print) Brandy Sanchez

Inspector (sign) _____

Inspector (print) S. Kyle

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS

Board of Pharmacy

ORIGINAL CERTIFICATE

Retail Pharmacy Permit

LICENSE NO. PHY 60872

ISSUE DATE 8/28/2025

WALGREENS SPECIALTY PHARMACY #15987
1020 29TH ST #140
SACRAMENTO, CA 95816

The above is licensed with the State Board of Pharmacy as a Corporation

BIJU DENNY CHACKO — PHARMACIST IN CHARGE

The official status of this license can be verified at www.pharmacy.ca.gov

PLACE RENEWAL LICENSE HERE

VALID UNTIL 8/1/2026

RECEIPT NUMBER 00792221

This original license must be kept for the life of the license and posted in public view.

In accordance with the provisions of Chapter 9 of Division 2 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is non-transferable. Contact the California State Board of Pharmacy when there is change of ownership, location, corporate officer, director, or shareholder (more than 10 percent share change), administrator or pharmacist-in-charge.

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

----- POST IN PUBLIC VIEW -----

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 60872

NAME: WALGREENS SPECIALTY PHARMACY #15987

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

1020 29TH ST #140
SACRAMENTO CA 95816
SACRAMENTO COUNTY

ISSUANCE DATE

AUGUST 28, 2025

EXPIRATION DATE

AUGUST 1, 2027

CURRENT DATE / TIME

JULY 30, 2026
8:22:46 AM

LICENSE RELATIONSHIPS

NAME: WALGREENS CO

LICENSE/REGISTRATION TYPE: UNKNOWN TYPE

LICENSE NUMBER: 90 **PRIMARY STATUS:** CLEAR

ADDRESS :

108 WILMOT RD
UNDEFINED
DEERFIELD IL 60015
OUT OF STATE COUNTY

NAME: BIJU, DENNY CHACKO

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 87616 **PRIMARY STATUS:** CLEAR

ADDRESS NOT DISCLOSED

Walgreens

Walgreen Co.
Corporate Office
200 Wilmot Road
Deerfield, IL 60015
www.walgreens.com

January 01, 2026

Walgreen Co. ("Walgreens") has operated retail drug stores since 1901. Walgreens and its wholly owned subsidiaries currently own and operate over 8,100 stores in the United States and Puerto Rico.

In the normal course of its business operations, Walgreens' pharmacies are periodically subject to inspection and, on occasion, administrative action by state agencies that regulate the practice of pharmacy. Typically, the pharmacy is given an opportunity to correct the deficiency within a specified period of time and, if it does so, the matter is closed without disciplinary or adverse licensure action.

During the course of the last reporting period, one or more pharmacies owned directly or indirectly by Walgreen Co. have been disciplined and/or required, as part of a corrective action plan, to pay an administrative fine to a state and/or federal agency. We can confirm, however, that none of the pharmacies subject to these actions had their retail pharmacy license in any way suspended, restricted, or denied as a result.

4VV

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application
Non-Refundable $500.00 Fee

Rev (03/17/2026)

Type of Facility

- ■ Ambulatory Surgical Center (ASC)
- ☐ Recovery Center (RC)

Type of Application (check applicable box)		Ownership Type (check applicable box)
■ New ASC/RC	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9)
☐ Location Change *		☐ Partnership (complete sections 1, 2, 5, 7, 8, 9)
☐ Name Change*	_____	■ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Pecos Surgery Center LLC

Physical Address: 3235 E Warm Springs Rd Suite 110

City: Las Vegas State: NV Zip: 89120

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 775-299-4787 Fax: 775-299-3024

Contact Email: pecossurgerycenter@gmail.com Website n/a

Nevada Business License # NV20263590297

Employed/Contracted Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

Medical Director Name: Adedayo Mokuolu M.D.

Days of Operation

■ Monday	■ Tuesday	■ Wednesday	■ Thursday	■ Friday	■ Saturday	☐ Sunday

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 3: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ■ No

Section 5: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Sole Owner

Owner's Name: Adedayo Mokuolu M.D.

Business Name: Pecos Surgery Center, LLC

Business Address: 3235 E Warm Springs Rd Suite 110

City: Las Vegas State: NV Zip: 89120

Telephone: 775-299-4787 Email: pecossurgerycenter@gmail.com

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Michelle McCarthy RPh NV Pharmacist License #: 22808

As the employed/contracted pharmacist, for (ASC/RC Name): Pecos Surgery Center, LLC :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.477;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.486;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. **Provide all the following *<u>where applicable</u>*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Michelle McCarty

Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

3-3-26

Date

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

As the employed/contracted pharmacist, for (ASC/RC Name): Pecos Surgery Center :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the top four stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**		✓		
• **For General Partnerships, list the name of each partner. NAC 639.214(2)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** ○ **All General Partners;** ○ **All Limited Partners who hold 10% or more of the interest.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.**	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Adedayo Mokuolu M.D

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

6/25/24

Date

Board Use Only	Date Received: 9/14/26	Amount: 500.00 / V#7820

SECRETARY OF STATE

STATE OF NEVADA

DOMESTIC LIMITED-LIABILITY COMPANY (86) CHARTER

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that **Pecos Surgery Center LLC** did, on 06/05/2026, file in this office the original Articles of Organization that said document is now on file and of record in the office of the Secretary of State of the State of Nevada, and further, that said document contains all the provisions required by the law of the State of Nevada.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 06/05/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate
Number: B202606056730491
You may verify this certificate
online at https://www.nvsilverflume.gov/home

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Pecos Surgery Center LLC

Nevada Business Identification # NV20263590297
Expiration Date: 06/30/2027

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 06/05/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202606056730492
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Pecos Surgery Center LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 3235 E Warm Springs Rd Suite 110

City Las Vegas State NV Zip 89120

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 7752994787 Website _____

Licensing Company Email pecossurgerycenter@gmail.com

Section 2: Personal Information

First Adedayo Middle O Last Mokuolu

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Henderson State NV Zi[redacted]

Telephone [redacted] Emai[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
College Of Medicine University Of Ibadan		10/1980 to 11/1986	
Address	**City**	**State**	**Zip**
Ibadan Nigeria			
Diploma/Degree obtained, if any			
Bachelor of Medicine and Surgery			

School Name		From - To (MM/YY – MM/YY)	
Kings College		10/79 to 10/1980	
Address	**City**	**State**	**Zip**
Lagos, Nigeria			
Diploma/Degree obtained, if any			
Advanced Level- Physics, Chemistry and Biology			

School Name		From - To (MM/YY – MM/YY)	
Hussey College		10/1974 to 10/1979	
Address	**City**	**State**	**Zip**
Warri, Nigeria			
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Desert Gastroenterology Associates			03/2013 to current
Business Address	**City**	**State**	**Zip**
2625 Wigwam Pkwy Ste 112	Henderson	NV	89074
Phone	**Title**		
702-255-5900	president		
Description of Duties			
Owner/President of Desert Gastroenterology Assoc.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Adedayo Mokuolu

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/26/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, ADEDAYO MOKUOLU, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

08/26/26

Date

Subscribed and Sworn to before me this 26th day of August 2026.

Notary Public Signature

RAPHAEL A. BONELLA II
Notary Public, State of Nevada
No. 22-1668-01
My Appt. Exp. Feb 2, 2030

(Seal)

4WW

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacist to Engage in the Practice of Pharmacy at a Site other than a Licensed Pharmacy

Rev (04/18/2023)

This application cannot be returned by fax or email.
We must have an original signature to process.

Section 1: Select the following that applies to you.

- ☐ I am employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity (If you marked this as your answer complete sections 1, 2, 3, 5, 7)
- ☐ I am a pharmacist who is employed by or under contract with a Nevada licensed pharmacy located within a hospital or correctional institution (If you marked this answer complete section 1, 2, 3, 5, 7)
- ☑ I am NOT employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity (If you marked this as your answer complete sections 1, 2, 4, 5, 6, 7)

Section 2: General Information

First: Kreshimir Middle: Louis Last: Rogina

NV Pharmacist Registration # 16721

Telephone: [redacted] Email: [redacted]

Section 3: Nevada Licensed Pharmacy as defined in NRS 639.012, or Nevada State Government Entity Information

Pharmacy/State Government Entity Name:

NV Pharmacy License # (if Pharmacy) or State Issued License # (if State Government Entity):

Address:

City: State: Zip:

Employer Contact Name:

Employer Contact Telephone: Employer Contact email:

Section 4: Employer Information

Name or Identity of Employer or Business as registered with the Nevada Secretary of State chapter 76 of NRS:

CareSource

Address: 112 North Curry St

City: Carson City State: NV Zip: 89703

Employer Contact Name: Kreshimir Rogina

Employer Contact Telephone: 17752504518 Employer Contact email: Kreshimir.Rogina@caresource.com

Section 5: Place where the Pharmacist will Engage in the Practice of Pharmacy (list all sites)

Name of Site (if applicable): _____

Address: [redacted]

City: Reno State: NV Zip [redacted]

Country/Territory/Province: USA

Is this a medical, residential, or business site? ☐ Medical ☒ Residential ☐ Business

Days of the week and hours services will be provided at this site? M-F; Varies

---

Name of Site (if applicable): _____

Address: 5470 Kietzke Ln Suite #208

City: Reno State: NV Zip: 89511

Country/Territory/Province: USA

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☒ Business

Days of the week and hours services will be provided at this site? M-F; Varies

---

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____

Address: _____

City: _____ State: _____ Zip: _____

Country/Territory/Province: _____

Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business

Days of the week and hours services will be provided at this site? _____

(Use and make copies of this page if necessary)

Section 6: NAC 639.403 A registered pharmacist who is NOT employed by or under contract with a pharmacy and who is NOT an employee of the State Government MUST complete this section.
1. Provide a description of the services that you intend to provide at the site, to include only those services listed in Section 7 (A) of this application. Plan Benefit Administration.
2. Provide the identification of the types of patients or other persons to whom you intend to provide services. CareSource Medicaid and marketplace members.
3. Provide a description of all resources, both paper and electronic, that will be available to you in the course of providing the services. CareSource systems, analytics tools, and other electronic resources necessary to perform pharmacy benefit administration functions
4. Provide an explanation of the policy for users of the services when you are unavailable. CareSource pharmacy operations maintains business processes.
5. Provide an explanation of the policy regarding the confidentiality and security of the patient data that will be gathered, made, and maintained as part of the services which are provided, including without limitation, paper and electronic records. All member information is maintained in secure CareSource systems and protected in accordance with applicable privacy, security, and HIPAA requirements.
6. Provide a description of the business plan for the services provided. Provide oversight and administration of pharmacy benefit operations for CareSource members, including supporting regulatory compliance and operational performance

Section 7: Laws pertaining to engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy. Please read Section 7 in its entirety. By signing this application, you attest you have read and understood the components in this section.

A. NAC 639 - For all registered pharmacists engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy

1. While engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy, a registered pharmacist may perform only:
    a. The functions described in paragraphs (b), (c), (d) and (g) to (j), inclusive, of subsection 1 or NRS 639.0124, except for dispensing or administering drugs;
    b. The functions described in section 4 of LCB File No. R036.21, except for dispensing a self-administered hormonal contraceptive; and
    c. The administration of immunizations pursuant to a written protocol established in accordance with NAC 639.297 to 639.2978, inclusive.
2. A registered pharmacist who engages in the practice of pharmacy at a location other than the site of a licensed pharmacy shall:
    a. Provide written notice of the site of practice to the Executive Secretary in accordance with NAC 639.225 on this application; (NAC 639.225 states that a Nevada pharmacist, within 10 days after changing residence or place of practice, must give written notice of the change to the Board.)
    b. Ensure that the records of the registered pharmacist are made readily accessible to members of the Board and employees, agents and designees of the Board; and
    c. Comply with all applicable federal and state laws and regulations, including, without limitation:
        i. The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and the regulations adopted pursuant thereto, and any other applicable federal or state law concerning the privacy of information regarding health care; and
        ii. Requirements relating to the maintenance or records.
3. A registered pharmacist who engages in the practice of pharmacy at a location other than the site of a licensed pharmacy shall not maintain an inventory of drugs at that location.
4. A registered pharmacist shall not engage in the practice of pharmacy at a location other than the site of a licensed pharmacy if he or she:
    a. Serves as a managing pharmacist; or
    b. Provides pharmaceutical services at:
        i. A facility for modified medical detoxification, as defined in NRS 449.00385;
        ii. An independent center for emergency medical care, as defined in NRS 449.013;
        iii. A facility for intermediate care, as defined in NR5 449.0038;
        iv. A facility for skilled nursing, as defined in NRS 449.0039; or
        v. A surgical center for ambulatory patients, as defined in NRS 449.019.

B. NAC 639 - For a registered pharmacist who is employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity.

For a registered pharmacist who is employed by or under contract with a pharmacy or who is an employee of the State Government may engage in the practice of pharmacy at a location other than the site of a licensed pharmacy shall not engage in the practice of pharmacy at a location other than the site of a licensed pharmacy unless he or she is provided with the same computerized system and access to data regarding a patient for whom a prescription has been submitted that is available to a registered pharmacist in the pharmacy. Such data must include, without limitation:

a. A legible copy of the prescription that is available as an electronic copy or a scanned image in the computerized system of the pharmacy or by facsimile machine; and
b. Any information that is available in the computerized system of the pharmacy that is relevant or necessary for the registered pharmacist to provide pharmaceutical services.

C. NAC 639.403 - For a registered pharmacist who is NOT employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity.

For a registered pharmacist who is NOT employed by or under contract with a pharmacy or who is an employee of the State Government shall not engage in the practice of pharmacy at a site other than the site of a licensed pharmacy unless he or she obtains the approval of the Board to engage in the practice of pharmacy at a site other than the site of a licensed pharmacy. To request such approval, the registered pharmacist must submit this application. The application must be approved before a registered pharmacist may commence any practice.

D. NAC 639.4916 - For a registered pharmacist who is employed by or under contract with a Nevada licensed pharmacy located within a hospital or correctional institution.

1. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide the remote chart order processing services to the hospital or correctional institution that the pharmacy is required by NAC 639.4915 to provide must:
    a. Be trained in the policies and procedures of the hospital or correctional institution regarding all policies and procedures of the hospital or correctional institution with which the registered pharmacist must comply, including, without limitation, the provisions of pharmaceutical services, security, and confidentiality of patient records; and
    b. Be provided with the same computerized system and access to data regarding a patient for whom a chart order has been submitted that would be available to a registered pharmacist employe by the pharmacy located within the hospital or correctional institution, including, without limitation:
        i. The height, weight and age of the patient and any allergies that the patient may have;
        ii. The medical records regarding any medications prescribed to the patient;
        iii. The results of any relevant laboratory tests;
        iv. The health history and notes regarding physical examinations, to the extent that the information is available in the computerized system of the hospital or correctional institution;
        v. Any notes provided by a physician, nurse or other medical staff of the institution, to the extent that those notes are available in the computerized system of the hospital or correctional institution;
        vi. A legible copy of the chart order that is available through a scanned image in the computerized system of the hospital or correctional institution or by facsimile machine; and
        vii. Any other information that is available in the computerized system of the hospital or correctional institution that is relevant or necessary for the registered pharmacist to provide pharmaceutical services.
2. Before a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution provides remote chart order processing services to the hospital or correctional institution, the registered pharmacist must review any relevant information regarding the patient for whom a chart order has been submitted. The registered pharmacist must, before approving a chart order to be filled, evaluate:
    a. The overutilization or underutilization of a medication;
    b. Therapeutic duplication;
    c. The appropriateness of the prescribed dosage and route of administration;
    d. The appropriateness of the directions for use of the medication;
    e. The appropriateness of the duration of the treatment with the prescribed medication;
    f. Any contraindication of the medication and a particular disease, ailment or allergy of the patient;
    g. Any contraindication or interactions between multiple medications prescribed for the patient; and
    h. The potential abuse or misuse of a medication.
3. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution provides remote chart order processing services to the hospital or correctional institution shall comply with the requirements of Section 7 (A) to the same extent as a registered pharmacist engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy pursuant to the provisions in Section 7 (B) and Section 7 (C).
4. In an emergency, a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution may render remote chart order processing services without being provided with all the information required by paragraph (b) of subsection 1 of Section 7 (D) if the registered pharmacist believes, in his or her professional judgement, that he or she has received sufficient information from the staff of the hospital or correctional institution to render the services.
5. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution may refuse to approve the filling of a chart order if, in the judgement of the registered pharmacist, the chart order is not safe or reasonable for the patient. A registered pharmacist who refuses to approve the filling of a chart order pursuant to this subsection must notify the hospital or correctional institution as soon as practicable that he or she has refused to approve the filling of the chart order.
6. Each time that a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution

provides remote chart order processing services pursuant to this section, the registered pharmacist shall make a notation in the computerized system of the hospital or correctional institution that indicates:

a. The name or identifier of the registered pharmacist;
b. The date and time that the registered pharmacist provided the services and, if applicable, approved the filling of a chart order; and
c. The specific services provided by the registered pharmacist.

7. The managing pharmacist of a pharmacy located within a hospital or a correctional institution may limit the remote chart order processing services provided pursuant to this section (Section 7 (D)).

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I attest to the knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. NRS 639.132

I understand that Nevada law requires a registered pharmacist who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Kreshimir L. Rogina

Print Name

Original Signature, no copies or stamps accepted

9/16/2026

Date

Board Use Only	Date Received: _____ For applicants who marked box 1 or 2 in Section 1: Executive staff to review, scanned into applicant file. For applicants who marked box 3 in Section 1: Executive staff to review, place on consent agenda.

5

ANNUAL DISCIPLINE CASES Reporting Period: January 2026 – June 2026			
FINDING	**HARM**	**DISCIPLINE INDIVIDUAL**	**DISCIPLINE FACILITY**
CVS is responsible for the acts of its employees who made an error in a prescription that results in negative outcome to the patient.	Yes	N/A	Respondent fined $10,000 for the violations; and assessed $1,000 in attorney's fees and costs.
Respondent KA made an error in a prescription that resulted in negative outcome to the patient.	Yes	Respondent's Certificate of Registration No. 19679 is suspended for a period of one year. The suspension is stayed, and Respondent is placed on probation subject to the following conditions: 1) Respondent fined $2,000 for the violations; 2) Respondent assessed $500 in attorney's fees and costs; and 3) Respondent shall comply with all federal and state statutes and regulations regarding the practice of pharmacy, and have no additional charges filed against him.	N/A
Respondent RA allowed non-practitioners to independently access, possess, furnish, and administer dangerous drugs without direct practitioner supervision.	No	Respondent's Certificate of Registration No. CS30228 is suspended for a period of one year. The suspension is stayed, and Respondent is placed on probation subject to the following conditions: 1) Respondent shall accept the Stipulation and Order is a public reprimand; 2) Respondent fined $5,000 for the violations; 3) Respondent assessed $1,000 in attorney's fees and costs; 4) Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against her while on probation.	N/A

Respondent CL prescribed dangerous drugs to patients with whom Respondent had not established a bona fide therapeutic relationship and failed to timely report disciplinary action.	No	Respondent's Certificate of Registration No. CS31815 is suspended for a period of one year. The suspension is stayed and Respondent is placed on probation subject to the following conditions: 1) Respondent shall accept the Stipulation and Order as a public reprimand; 2) Respondent fined $5,000 for the violations; 3) Respondent assessed $1,000 in attorney's fees and costs; 4) Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.	N/A
Respondent GO dispensed controlled substances without a valid dispensing practitioner registration and failed to review PMP.	No	Respondent's Certificate of Registration No. CS35044 is suspended for a period of one year. The suspension is stayed and Respondent is placed on probation subject to the following conditions: 1) Respondent shall accept the Stipulation and Order as a public reprimand; 2) Respondent fined $5,000 for the violations; 3) Respondent assessed $1,000 in attorney's fees and costs; 4) Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.	N/A
As pharmacy/pharmacy owner, Costco Pharmacy is responsible for the acts of its employees who made an error in a prescription.	Yes	N/A	Respondent fined $2,000 for the violations; and assessed $1,000 in attorney's fees and costs.
Respondent CV made an error in a prescription.	No	Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A

Respondent DY allowed a non-practitioner to independently access, possess, furnish, and administer dangerous drugs without direct practitioner supervision.	No	Respondent's Certificate of Registration No. CS06454 is placed on probation for one year subject to the following conditions: 1) Respondent shall accept the Stipulation and Order is a public reprimand; 2) Respondent fined $5,000 for the violations; 3) Respondent assessed $1,000 in attorney's fees and costs; 4) Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.	N/A
The Nevada BOP took reciprocal disciplinary action on AW's Certificate of Registration No. 22724 based upon disciplinary action by the Arizona Board of Pharmacy for diversion.	No	Respondent's Certificate of Registration No. 22724 is placed on probation until October 29, 2029, and Respondent shall fully comply with the Arizona BOP Consent Order in Case No. 24-0394. Respondent fined $1,000 for the violations.	N/A
As pharmacy/pharmacy owner, SP is responsible for the acts of its employees who mailed dangerous drugs in California, Louisiana, Ohio, Texas, and Wisconsin when they did not hold a pharmacy, wholesaler, or mail pharmacy license in those states.	No	N/A	Respondent accepts the Stipulation as a public reprimand. Respondent has forfeited License No. PH03880 when they failed to renew their license on November 1, 2020. Respondent fined $5,000 for the violations and assessed $1,000 in attorney's fees and costs.
As managing pharmacist during the time of the events, Respondent TA was aware and is responsible for the acts of its employees who mailed dangerous drugs in California, Louisiana, Ohio, Texas, and Wisconsin when they did not hold a pharmacy, wholesaler, or mail pharmacy license in those states.	No	Respondent's Certificate of Registration No. 19070 is revoked. The revocation is stayed and Respondent is placed on probation subject to the following conditions: 1) Respondent fined $2,000 for the violations; 2) Respondent assessed $1,000 in attorney's fees and costs; 3) Respondent shall complete two additional hours of continuing education on duties of a managing pharmacist; and 4) As a condition or probation, Respondent shall not engage in any conduct for which disciplinary action may be imposed pursuant to the provisions.	N/A

Respondent RM dispensed dangerous drugs without a dispensing registration; held for sale an adulterated drug; failed to produce complete and accurate records of all dangerous drugs dispensed to patients; failed to store and/or possess dangerous drugs from patients and employees that were not in stock containers properly labeled and procured from a manufacturer, wholesaler or pharmacy; and did not acquire the dangerous drugs from patients and employees pursuant to a prescription written by himself or another practitioner, and/or were not dispensed to Respondent by a pharmacy or dispensing practitioner.	No	Respondent accepts the Stipulation as a public reprimand. Respondent fined $5,000 for the violations and assessed $500 in attorney's fees and costs.	N/A
Respondent EW failed to disclose on his 2022 controlled substance application renewal that he had been subject to disciplinary action before numerous state boards of medicine.	No	Respondent fined $1,000 for the violations.	N/A
As pharmacy/pharmacy owner, WP is responsible for the acts of its employees who made an error in a prescription that resulted in a negative outcome to the patient.	Yes	N/A	Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs. Respondent will ensure all pharmacies in Nevada that use automated filling cells required pharmacists to review the SOPs for filling automated cells with medications from stock bottles within 60 days of the effective date of the Order. In addition, Walgreens #8342 will cease using the Yuyama EV-1 automated filling cells as of January 31, 2026.

As managing pharmacist during the time of the events, Respondent DW is responsible for the acts of its employees at Partell Pharmacy who dispensed invalid “Emergency Kits” or “COVID Kits” for which the drugs in each kit were not identified on the prescription, and they would substitute Budesonide in the “COVID Kit” with a Medrol DosePak and Albuterol without the knowledge or consent of the prescribing practitioner.	No	Respondent accepts this Stipulation as a public reprimand; Respondent’s Certificate of Registration No. 13635 has been forfeited since he failed to renew it on November 1, 2025; Respondent shall pay a fine of $5,000 for the violations; and assessed $1,000 in attorney’s fees and costs.	N/A
Respondent SS was arrested for a DUI and was under the influence of alcohol and Diazepam, a controlled substance. He did not have a valid U.S. prescription as he obtained the medication from a prescription issued by a licensed physician in Thailand. Respondent was disciplined by the California BOP where the Nevada BOP took reciprocal action.	No	Respondent accepts the Stipulation as a public reprimand; and assessed $500 in attorney’s fees and costs.	N/A
TU committed numerous violations related to controlled substances.	No	Respondent’s Certificate of Registration No. PD00512 is revoked. Respondent’s Certificate of Registration No. CS1604 is suspended for a period of two years. The suspension is stayed and Respondent is placed on probation subject to the following conditions: a) Respondent fined $5,000 for the violations; b) Respondent assessed $1,000 attorney’s fees and costs; and c) Respondent shall comply with all federal and status statues and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.	N/A

IG failed to timely renew his Certificate of Registration No. CS33713 prior to issuing controlled substance prescriptions and failed to review patient utilization reports in the PMP database prior to issuing controlled substance prescriptions.	No	Respondent subject to the following penalties: Public reprimand. Respondent's Certificate of Registration No. CS33713 is suspended for a period of two years. The suspension is stayed and Respondent is placed on probation subject to the following conditions: a) Respondent accepts the Stipulation and Order as a public reprimand; b) Respondent find $5,000 for the violations; c) Respondent assessed $1,000 in attorney's fees and costs; d) Respondent shall complete training with Board staff on the use of the PMP database within 60 days of the Order; and e) Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed again him while on probation.	N/A
SN failed to disclose prior Iowa Board of Nursing disciplinary action on her 2022 Nevada controlled substance application. She also issued at least 148 prescriptions between April 18, 2024, and June 11, 2024, without a valid Nevada DEA registration and without a registered practice location on file with the Board. In addition, she did not timely report her 2025 disciplinary action from the Nevada Board of Nursing. Finally, she unlawfully accessed the PMP database and disseminated a patient utilization report for J.S., with whom she had no bona fide therapeutic relationship.	No	Respondent 's Certificate of Registrations No. CS34530 and PR16791 are revoked. Respondent fined $5,000 for the violations; and assessed $1,500 in attorney's fees and costs.	N/A
As pharmacy/pharmacy owner, Respondent purchased prescription drugs from pharmacies not licensed for wholesale distribution in Nevada.	No	N/A	Respondent accepts the Stipulation and Order as a public reprimand. Respondent fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs.

As managing pharmacist at the time of the events of January 2023 and October 2023, NS purchased prescription drugs from pharmacies not licensed for wholesale distribution in Nevada.	No	Respondent accepts the Stipulation and Order as a public reprimand. Respondent fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs. Respondent shall complete two additional CE hours on duties of a management pharmacist.	N/A
As managing pharmacist at the time of the events of December 2023 and April 2024, KB purchased prescription drugs from pharmacies not licensed for wholesale distribution in Nevada.	No	Respondent accepts the Stipulation and Order as a public reprimand. Respondent fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs. Respondent shall complete two additional CE hours on duties of a management pharmacist.	N/A
JO allowed an employee to perform duties of a dispensing technician in training without the required registration.	No	Respondent's Certificate of Registration No. CS15479 and PD15479 are suspended. The suspension is stayed and placed on probation for a period of one year subject to the following conditions: a) Respondent shall pay a fine of $2,000 for the violations; and b) Respondent shall pay $500 in attorney's fees and costs.	N/A
AP made an error in a prescription while using virtual verification.	No	Respondent fined $500 for the violations; and assessed $500 in attorney's fees and costs.	N/A
TS made an error in a prescription while using virtual verification.	No	Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A
As managing pharmacist at the time of the events, GS filled prescriptions that were not valid from October 22, 2025, to November 4, 2025.	No	Respondent accepts the Stipulation and Order as a public reprimand. Respondent fined $2,500 for the violations; and assessed $750 in attorney's fees and costs. Additionally, Respondent agrees to participate in training with Board staff on laws related to controlled substances.	N/A
RC made an error in a prescription that resulted in a negative patient outcome. Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	Yes	Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A

As pharmacy/pharmacy owners, CVS is responsible for the acts of its employees who made an error in a prescription that resulted in a negative patient outcome.	Yes	N/A	CVS fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.
As pharmacy/pharmacy owner, CVS is responsible for the acts of its employees who made an error in a prescription while using virtual verification.	No	N/A	CVS fined $5,000 for the violations; and assessed $500 in attorney's fees and costs. In addition, CVS corporate management shall provide the Board's staff with copies of written policies, procedures, training manuals or other materials, if any, that specifically confirm or corroborate its contention that all CVS pharmacists in Nevada have the discretion to perform visual inspections by physical or manual manipulation of prescription drug products before dispensing them to patients. If no such policies, procedures, training manuals or other materials exist, CVS shall provide a written statement to that effect. Additionally, CVS corporate management shall provide a written statement or summary of its plan, if any, to provide ongoing periodic reminders to or conduct training with its pharmacists concerning their discretion to perform visual inspections by physical or manual manipulation of prescription drug products before dispensing them to patients. If no such plan exists, CVS shall provide a written statement to that effect.
As pharmacy/pharmacy owner, RP is responsible for the acts of its employees who made an error in a prescription that resulted in a negative outcome to the patient.	Yes	N/A	RP fined $10,000 for the violations; and assessed $1,000 in attorney's fees and costs.

OS made an error in a prescription that resulted in a negative outcome to the patient.	Yes	OS fined $2,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A
MF was disciplined by the Pennsylvania Board of Pharmacy for submitting altered endotoxin and sterility test certificates for equine glucosamine injections and for misrepresenting acceptable levels to FDA inspectors. The Nevada Board of Pharmacy imposed reciprocal discipline.	No	MF's Certificate of Registration No. 22316 is placed on probation for a period of one year; and assessed $1,000 in attorney's fees and costs.	N/A
As pharmacy/pharmacy owner, CVS #8792 is responsible for the acts of its employees who made an error in a prescription.	No	N/A	CVS fined $2,000 for the violations; and assessed $1,000 in attorney's fees and costs.
As the supervising pharmacist, JL is responsible for the acts of an intern pharmacist who made an error in a prescription.	No	JL fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A
FE was convicted of a federal offense involving the unlawful conversion of Medicare funds for personal use.	No	FE's Certificate of Registration No. CS23430 is suspended through October 31, 2026.	N/A
GZ provided false information on her Pharmaceutical Technician-in-Training application by claiming she had obtained a high school diploma or GED, despite never having completed or received either credential.	No	GZ's Certificate of Registration No. PT28532 is cancelled; and assessed $586.34 in attorney's fees and costs.	N/A
As pharmacy/pharmacy owner, CVS #9586 is responsible for the act of a pharmacist who made an error in a prescription.	No	N/A	CVS fined $5,000 for the violations; and assessed $500 in attorney's fees and costs.
MP made an error in a prescription.	No	Respondent fined $1,000 for the violations and assessed $500 in attorney's fees and costs.	N/A

During Respondent ML's tenure as Premier Beauty's medical director, he rarely visited the spa while dangerous drugs were stored, ordered, and administered. Employees injected prescription medications without the medical director present, without a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug was medically necessary. Additionally, the spa also obtained drugs from an unlicensed Florida wholesaler and kept multiple injectable products intended for foreign markets and not approved for distribution or use in the United States.	No	ML accepts Stipulation as a public reprimand; fined $5,000 for the violations; assessed $1,000 in attorney's fees and costs; and cannot service as a medical director of any practice site in the State of Nevada where injectable dangerous drugs and controlled substances in possession of individuals who do not hold a license to possess them in Nevada for a period of years from the effective date of the Order.	N/A
PR did not check the PMP database for a patient's controlled-substance history or review the patient's utilization report before issuing a prescription. He also failed to review his own prescriber activity in the PMP system for the period between August 21, 2023, and August 12, 2025.	No	PR fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs. Additionally, Respondent must participate in PMP training within 60 days of the effective date of the Order.	N/A
LO was medical director of Skin Lab from April 23, 2023, to February 18, 2024, again from December 18, 2024, to May 31, 2025, and from June 1, 2025, to the present. During this time, Respondent allowed all employees unrestricted access to the facility's dangerous drug inventory and failed to maintain the security of the dangerous drugs within her possession.	No	LO fined $5,000 for the violations; assessed $500 in attorney's fees and costs. Additionally, Respondent cannot serve as medical director of any practice site in the State of Nevada where injectable dangerous drugs and controlled substances are in the possession of individuals who do not hold a license to possess them in Nevada for a period of five years from the effective date of the Order.	N/A
PA failed to document whether counseling was offered or provided for a dispensed prescription as required by state regulation.	No	PA fined $750; assessed $500 in attorney's fees and costs; and required to complete two continuing-education courses on pharmacy record-keeping.	N/A

AH, a licensed medical products provider, received a CPAP prescription for a patient in June 2024 but did not deliver the device until July 2025, despite billing the patient's insurer for its use from August to October 2024 and for additional supplies in 2025. The delay stemmed from an error in Respondent's system. AH's actions fell below Nevada's professional and billing standards, and AH also failed to document patient communications, respond timely to Board inquiries, and maintain required records.	No	N/A	AH fined $3,000 for the violations; and assessed $1,000 in attorney's fees and costs.
The pharmacy owner, NN, caused the assets of LP to be sold to RM on September 26, 2024, without providing the required advance notice to the Board or filing a change-of-ownership application, as mandated by Nevada Law. As a result, RM operated the pharmacy without a valid license, continuing to handle and dispense dangerous drugs and controlled substances unlawfully. LP is responsible for the acts of its employees who enabled unlicensed pharmacy operations.	No	N/A	LP's License No. PH04561 shall remain inactive.
The pharmacy owner, NN, sold its assets to MM on September 19, 2025, without providing the required advance notice to the Board or filing a change-of-ownership application, as mandated by Nevada Law. Also, a pharmacist processed at least ten prescriptions lacking information required under Nevada law. TP is responsible for the acts of its employees who enabled unlicensed pharmacy operations and processed ten prescriptions without the required information required by Nevada Law.	No	N/A	TP's License No. PH04648 shall remain inactive.

As pharmacy owner, NN sold the pharmacy assets for LP to RM on September 26, 2024, and the pharmacy assets for TP to MM on September 19, 2025, without providing the required advance notice to the Board or filing a change-of-ownership application, as mandated by Nevada Law.	No	NN's Certificate of Registration No. 20601 is suspended; however, the suspension is stayed. Respondent NN is placed on probation for a period of two years from the effective date of the Order subject to the following conditions: 1) pay a fine of $5,000 for the violations; 2) pay $2,000 in attorney's fees and costs; and 3) as a condition of probation, NN shall not engage in any conduct for which disciplinary action may be imposed. Additionally, NN may not own a pharmacy in Nevada for a period of three years from the effective date of the Order. NN shall seek Board approval for any ownership of a pharmacy after the prohibition of ownership has ended.	N/A
RG was disciplined by the Nevada Board of Pharmacy on October 11, 2023, and placed on five years of probation with a requirement to complete substance-abuse counseling and provide proof of progress. He failed to renew his certificate of registration on November 1, 2024, and thereafter failed to provide proof of continuing participation in substance-abuse counseling.	No	As a result, Certificate of Registration No. CS27126 is revoked retroactively to October 31, 2024, and RG may not petition for reinstatement until April 15, 2027.	N/A
SA was the medical director of Youth, Inc. During this period, the owner and/or employees stored and possessed prescription drugs and administered injectable prescription drugs at times when no practitioner was on-site. Respondent accepts this Stipulation as a public reprimand for having assisted or permitted the unauthorized storage, possession and administration of drugs.	No	SA fined $5,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A

Respondent JE verified prescriptions that did not comply with Nevada law, thus causing his employer, Meta Pharmacy, to dispense dangerous drugs and controlled substances to Meta's customers without proper medical authorization.	No	Respondent's Certificate of Registration No. 20782 is revoked; however, the revocation is stayed, and Respondent is placed on probation for a period of two years beginning June 3, 2026. Respondent fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs. In addition, Respondent must complete four continuing education credit hours on the topic of ethics in the practice of pharmacy and must refrain from any conduct that could subject him to further disciplinary action.	N/A
Respondent TH permitted non-practitioner owners, managers, and/or employees to engage in unregistered prescribing, failed to establish and maintain effective controls against diversion of controlled substances, and failed to query the PMP database as required by Nevada Law. Respondent was noticed to appear at the Board's meeting on June 3, 2026, but she failed to appear and a default hearing was held.	No	Respondent's Certificate of Registration No. CS25791 is revoked, and Respondent cannot petition for reinstatement for a period of one year. Respondent fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs.	N/A
As pharmacy/pharmacy owner, RP is responsible for the acts of its employees who failed to document whether counseling was offered or provided for a dispensed prescription as required by state regulation.	No	N/A	Respondent fined $750; assessed $500 in attorney's fees and costs. Respondent has cooperated, and it agrees to cooperate with the Board's inspectors in terms of explaining and/or demonstrating how its systems for documenting patient counseling operates and to make reasonable changes or modifications to that system, as appropriate, to address any compliance concerns that the Board may have.
As pharmacy/pharmacy owner, PP is responsible for the acts of its employees who failed to correct a data entry error related to a prescription for a maintenance medication needed by a patient of the	Yes	N/A	Respondent fined $1,500 for the violations; and assessed $1,732 in attorney's fees and costs.

MorningStar assisted living facility. The failure to correct the error caused a lengthy interruption to the patient's medication therapy and resulted in a negative medical outcome to the patient.			
In Case No. 24-370-RPH-N, Respondent CK failed to correct a data entry error related to a prescription for a maintenance medication needed by a patient of the MorningStar assisted living facility. The failure to correct the error caused a lengthy interruption to the patient's medication therapy and resulted in a negative medical outcome to the patient. Additionally, in Case No. 26-084-RPH-N, Respondent CK was found to be intoxicated while on duty. The allegations in both cases were consolidated and settled by way of a stipulation.	No	Per the stipulation, Respondent's Certificate of Registration No. 19388 is revoked. The revocation is stayed and Respondent is placed on probation until June 30, 2028 subject to the following conditions: 1) Respondent shall participate in a professional monitoring program as recommended by her practitioner and for quarterly reports to be sent to Board staff; 2) If requested by the Board, Respondent will appear before the Board prior to her 2027 certificate-of-registration renewal to answer questions regarding her progress and participation in the professional monitoring program; 3) Respondent shall pay a fine of $1,000 for the violation alleged in Case No. 24-370-RPH-N; and assessed a total of $1,500 in attorney's fees and costs for the violations alleged in Case Nos. 24-370-RPH-N and 26-084-RPH-N.	N/A
As pharmacy/pharmacy owner, WP is responsible for the acts of its employees who made an error in a prescription.	No	N/A	Respondent fined $2,000 for the violations; and assessed $1,000 in attorney's fees and costs.
Respondent MM made an error in a prescription.	No	Respondent's Certificate of Registration No. 23854 is suspended. The suspension is stayed and is placed on a probation for a period of two years from the effective date of the Order. Respondent fined $2,000 for the violations; and assessed $1,000 in attorney's fees and costs. Respondent shall not engage in any conduct for which disciplinary action may be imposed.	N/A
PPLP engaged in unlawful wholesale distribution of prescription drugs in Nevada.	No	N/A	Respondent appealed the Citation and Fine at the June 3, 2026, Board Meeting where the Board upheld the $5,000 fine.

Respondent AG failed to query the PMP prior to issuing controlled substance prescription, allowed unauthorized person to his credential to access the PMP Database, and failed to query and review his MyRx prescriber activate in the PMP.	No	Certificate of Registration No. CS09380 is placed on probation for a period of two years subject to the following conditions: 1) Respondent accepts this Stipulation and Order as a public reprimand; 2) Respondent fined $5,000 for the violations; 3) Respondent assessed $1,000 in attorney's fees and costs; and 4) Respondent shall complete PMP training within 60 days from the Order and shall complete follow up training six months after initial training.	N/A
HV engaged in the sale and distribution of opthalmic products that did not follow FDA regulations and were manufactured at a facility not registered by the FDA even after the FDA issued a warning letter.	No	N/A	Respondent fined $2,500; and assessed $1,000 in attorney's fees and costs.
Respondent PS failed to disclose her discipline on her 2023 pharmaceutical technician in training application. A hearing was held on June 3, 2026, but she failed to appear and a default hearing was heard.	No	Respondent's Certificate of Registration No. PT28814 is revoked and may not petition for reinstatement for a period of one year from the effective date of the Order. Respondent shall appear before the and answer questions and give testimony regarding her application and her compliance with her Order. Respondent assessed $1,118.15 in attorney's fees and costs.	N/A
At the time of the events, Respondent JS was the managing pharmacist who made false statement to the Nevada Board of Pharmacy Inspector during an inspection of Modern Rx. A hearing was held on June 3, 2026, but he failed to appear and a default hearing was heard.	No	Respondent's Certificate of Registration No. 18852 is revoked and may not petition for reinstatement for a period of one year from the effective date of the Order. Respondent shall appear before the Board and answer questions and give testimony regarding his application and his compliance with his Order. Respondent assessed $190.95 in attorney's fees and costs.	N/A

Respondent DH failed to disclose criminal history on her 2014 pharmaceutical technician in training application and subsequently on all her biennial renewal applications through 2022. A hearing was held on June 3, 2026, but he failed to appear and a default hearing was heard.	No	Respondent's Certificate of Registration No. PT27744 is revoked and may not petition for reinstatement for a period of one year from the effective date of the Order. Respondent shall appear before the Board and answer questions and give testimony regarding her application and her compliance with ger Order. Respondent assessed $1,261.84 in attorney's fees and costs.	N/A

5A

FILED
JUL 2 1 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

MARILOU REYES, RPH,
Certificate of Registration No. 11763,

AND,

CVS PHARMACY #9168,
Pharmacy License No. PH00506,

Respondents.

Case No. 24-010-RPH-N
24-010-PH-N

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent Marilou Reyes ("Respondent Reyes"), because Respondent Reyes holds a certificate of registration issued by the Board pursuant to NRS 639.127, authorizing her to engage in the practice of pharmacy in the state of Nevada.

2. The Board has jurisdiction over CVS Pharmacy #9168 ("Respondent CVS" or "CVS"), because Respondent holds a license issued by the Board pursuant to NRS 639.230, authorizing Respondent CVS to operate a pharmacy located at 1119 California Ave., Reno, Nevada 90523.

FACTUAL ALLEGATIONS

3. On November 21, 2023, at approximately 9 a.m., patient L.A., a California resident, requested that prescriptions maintained by Kaiser Permanente Pharmacy in Los Angeles,

California ("Kaiser") be transferred on an emergency basis to CVS while she was visiting her sister in Reno.

4. While at CVS, L.A. informed two pharmaceutical technicians that she has epilepsy, had traveled without her medications, and needed an immediate transfer of her anti-seizure medication, Tegretol.

5. CVS technicians refused to contact Kaiser regarding the transfer request and informed L.A. that she should seek assistance from another, less busy, pharmacy.

6. L.A. remained at CVS and contacted Kaiser herself to initiate the transfer request.

7. Subsequently, Kaiser transferred, by way of facsimile, all of L.A.'s active prescriptions, totaling seven (7), two (2) of which were additional re-fills. The transferred medications included Tegretol, Metoprolol, Gabapentin, Levothyroxine (with additional re-fill), and Fluoxetine (with additional re-fill).

8. Respondent Reyes communicated directly with the Kaiser pharmacist regarding the transfer and accepted the facsimile transmission of the transferred prescriptions.

9. Kaiser records documented the successful facsimile transmission of all seven (7) transferred prescriptions to CVS. Kaiser also facsimiled detailed notes for each prescription, including the medication name, strength, quantity, and supply.

10. CVS utilizes an electronic facsimile system. All incoming facsimiles are initially placed in a queue pending retrieval by pharmacy staff. Once retrieved, the facsimile is printed and scanned, and the prescription information is then manually entered into CVS's pharmacy system.

11. CVS Pharmaceutical technician Shirley Donnelly only entered five (5) of L.A.'s seven (7) facsimiled prescriptions into its system and assigned prescription numbers for Gabapentin, Levothyroxine, Fluoxetine (with additional refill), and Metoprolol. Respondent Reyes verified the five (5) prescriptions.

12. While waiting for her prescription to be dispensed by CVS, L.A.'s condition deteriorated, and she became unable to effectively communicate.

13. After learning of L.A.'s condition during a telephone call with her, L.A.'s sister went to CVS at approximately 1:00 p.m. where she observed L.A. slumped over in a chair near the pharmacy counter unable to speak or otherwise communicate.

14. Shortly thereafter, a CVS employee dispensed Gabapentin, Levothyroxine, Fluoxetin, and Metoprolol to L.A.'s sister who immediately gave L.A. the medication while still in the pharmacy.

15. Later that day, L.A. experienced a seizure and was transported to Renown hospital by paramedics. The paramedics confirmed that none of the medications dispensed to Respondent earlier that day were to treat seizures.

16. During L.A.'s hospitalization, she experienced status epilepticus (continuous seizures), was admitted to the intensive care unit, and placed on a ventilator. She remained hospitalized from November 21, 2023 through November 24, 2023.

17. Following her discharge, L.A. experienced memory loss and was ordered to stop driving for six months.

18. Kaiser records reflect that L.A.'s Tegretol prescription had been transferred to Respondent CVS, while Respondent CVS records reflect no prescription for Tegretol.

19. The facsimile records maintained by CVS consisted of scanned pages marked "2/6," "3/6," "4/6", and "5/6." CVS did not maintain records of the pages marked "1/6" and "6/6", and Respondent CVS was unable to account for the missing pages or determine their contents.

20. CVS was further unable to retrieve the original transmission because facsimiles are immediately deleted from the system after they are entered into CVS's records. Pursuant to CVS's computer system, deleted facsimiles are moved to the "Delete Triage" and are only recoverable that same day.

21. CVS Corporate can only retrieve deleted records within 30 days of being sent to the "Deleted Triage."

PRIOR DISCIPLINE

22. In 1998, the Board disciplined Respondent CVS for a dispensing error and imposed a $400 fine.

23. In 2010, the Board disciplined Respondent CVS for a dispensing error and imposed a $1,000 fine.

24. In 2010, the Board disciplined Respondent CVS for mislabeling a prescription's directions, resulting in patient harm. The Board imposed a $750 fine.

APPLICABLE LAW

25. A pharmacist has a duty to review a patient's record before dispensing a prescription to determine its therapeutic appropriateness. NAC 639.707(4). The pharmacist may consider, among other things, diseases which the patient has.

26. A pharmacist has a duty to keep facsimile prescriptions for at least two (2) years after receipt. If the paper is not of sufficient quality to last for at least 2 years, the facsimile prescription must be reproduced on permanent paper, or the pharmacist must reduce the prescription to writing and attach the original transmission of the prescription to the reproduced copy or the prescription reduced to writing. NAC 639.711(5).

27. A pharmacist who receives a prescription to fill, including a prescription that is written, transcribed from an oral order or transferred to the pharmacy, shall mark on the prescription a unique serial number issued for that prescription. NAC 639.706(1).

28. A pharmacist shall maintain a physical record in the files of prescriptions that accurately explains or accounts for any serial number issued for a prescription that is not filled, including a serial number issued in error or for a prescription that is later rendered void. NAC 639.706(3).

29. A person who is issued a license to conduct a pharmacy shall ensure that the pharmacy uses a computerized system for recording information concerning prescriptions. NAC 639.924.

30. Any computerized system used by a pharmacy for recording information concerning prescriptions must be designed in such a manner that it provides a readily retrievable printed record of the information relating to a prescription or a patient which the pharmacy is required to maintain pursuant to state or federal law, including, without limitation, information relating to the original prescription or the refill or modification of that prescription. NAC 639.910(1)(a).

31. Any computerized system used by a pharmacy for recording information concerning prescriptions must be designed in such a manner that it provides a procedure that may be conducted at least once each day to ensure that the information which is recorded in the system is not lost or destroyed. NAC 639.910(1)(m).

32. Unprofessional conduct by a pharmacist includes, "performing any of his or her duties . . . in an incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

33. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

34. The Board may discipline a licensee who has violated any provisions of a regulation relating to the practice of pharmacy. NRS 639.210(12).

35. In lieu of, or in addition to, revoking or suspending a license holder's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

\\\

\\\

\\\

\\\

\\\

\\\

COUNT ONE
Unprofessional Conduct – Failure to Exercise Professional Judgment
(Respondents Reyes and CVS)

36. As alleged above, Respondent Reyes verified and dispensed only five (5) of L.A.'s seven (7) facsimile prescriptions, failing to verify and dispense, among others, L.A.'s prescription for Tegretol.

37. Respondent Reyes failed to locate L.A.'s prescription for Tegretol despite pharmacy staff being aware of L.A.'s epilepsy diagnosis and deteriorating condition near the pharmacy counter.

38. Based upon the foregoing, Respondent Reyes knew or reasonably should have known that L.A. was awaiting an anti-seizure medication, among others.

39. Respondent Reyes breached her duty under NAC 639.707(4) to evaluate whether the prescriptions that she had verified for L.A. were therapeutically appropriate to control L.A.'s epileptic seizures.

40. Had Respondent Reyes properly reviewed and considered L.A.'s known diagnosis of epilepsy and deteriorating condition when determining the therapeutic appropriateness of dispensing drugs that did not include an anti-seizure medication, Respondent Reyes likely would have discovered the omission to fill L.A.'s prescription for Tegretol.

41. As alleged above, Respondent Reyes performed her duties as a pharmacist in a negligent, unskillful or incompetent manner, thus engaging in unprofessional conduct.

42. As the owner/operator of the pharmacy at which Respondent Reyes was employed, Respondent CVS is responsible for Respondent Reyes' conduct as alleged above. Accordingly, the Board may discipline Respondent CVS pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

COUNT TWO
Unprofessional Conduct – Failure to Properly Serialize Prescriptions and/or Maintain Prescription Records Transmitted Via Facsimile (Respondents Reyes and CVS)

43. As the CVS pharmacist on duty on November 21, 2023, Respondent Reyes had a duty to assign unique serial numbers to each of the prescriptions transferred from Kaiser on behalf of L.A.

44. As the CVS pharmacist on duty on November 21, 2023, Respondent Reyes had a duty to generate a record or summary explaining or accounting for any serial numbers issued for prescriptions that were not filled by CVS for L.A.

45. As the CVS pharmacist on duty on November 21, 2023, Respondent Reyes had a duty to generate a record or summary documenting all the pertinent prescription information transferred from Kaiser on behalf of L.A.

46. Based upon the prescription information received from Kaiser, Respondent Reyes knew or reasonably should have known that there were seven (7) prescriptions requiring serialization and/or documentation. Respondent Reyes failed to serialize and/or document two of those prescriptions.

47. Given that L.A. was visibly distressed within the pharmacy, Respondent Reyes knew or reasonably should have known that it was critically important to fully and accurately serialize and document the prescriptions transferred from Kaiser on behalf of L.A.

48. By failing to fully and accurately serialize and document the prescriptions transferred from Kaiser on behalf of L.A., Respondent Reyes performed her duties as a pharmacist in a negligent, unskillful or incompetent manner, thus engaging in unprofessional conduct. NRS 639.210(4). See also NAC 639.945(1)(i).

49. As the owner/operator of the pharmacy at which Respondent Reyes was employed, Respondent CVS is responsible for Respondent Reyes' unprofessional conduct as alleged above. Accordingly, the Board may discipline Respondent CVS pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

COUNT THREE
Unprofessional Conduct – Failure to Maintain a Compliant Computerized System (Respondent CVS)

50. Respondent CVS had a duty to maintain a computerized system that has readily retrievable records and that has a procedure in place to ensure that recorded information is not deleted. NAC 639.910.

51. Respondent CVS performed its duties in an incompetent, unskillful, or negligent manner because it did not have a procedure in place to ensure that its original incoming facsimiles are readily retrievable. *See* NAC 639.910(1)(m); NAC 639.945(1)(i).

52. Having engaged in unprofessional conduct as alleged above, Respondent CVS is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration for Respondent CVS Pharmacy #9168 and Respondent Reyes.

DATED this 21st day of July 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9168,** **Pharmacy License No. PH00506,** **Respondent.**	**Case No. 24-010-PH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 2, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Amy Steelman, at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **aksteelman@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 21st day of JULY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #9168,** **Pharmacy License No. PH00506,** **Respondent.**	**Case No. 24-010-PH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

AUTHORIZED REPRESENTATIVE FOR CVS PHARMACY #9168

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 22nd day of July 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

CVS Pharmacy #9168
1119 California Ave.
Reno, NV 89509

And via courtesy email to: brian.convery@cvshealth.com

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARILOU REYES, RPH,** **Certificate of Registration No. 11763, and** **CVS PHARMACY #9168,** **Pharmacy License No. PH00506,** **Respondents.**	**Case Nos. 24-010-RPH-N** **24-010-PH-N** **STIPULATION AND ORDER** **[CVS PHARMACY #9168 ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through counsel, Amy K. Steelman, Esq., and CVS Pharmacy #9168, Pharmacy License No. PH00506, ("Respondent"), by and through counsel, Joseph Lavino, Esq., **HEREBY STIPULATE AND AGREE THAT:**

1. On or about July 23, 2026, Respondent was served with the Notice of Intended Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

2. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

3. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal, and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

4. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing, reconsideration, appeal, and any and all other rights related to this action that may be accorded by the

Nevada Administrative Procedure Act, Administrative Procedure Before Certain Regulatory Bodies, and the Nevada Pharmacy Act.

5. Respondent contests the allegations stated in Count One, Count Two, and Count Three the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein. This Stipulation shall not be construed as an admission of liability by Respondent nor a concession by the Board that the Accusation is not based upon sufficient evidence.

A. While acting as an employee of Respondent, Pharmacist Reyes verified and dispensed four facsimile prescriptions for patient L.A.

B. Kaiser reported that additional prescriptions, including L.A.'s prescription for Tegretol, were also faxed; CVS disputes that any additional prescriptions for L.A. were received. CVS contends that there is a lack of evidence that any additional prescriptions were successfully transmitted to or received by CVS, entered into any CVS system, or subsequently deleted by CVS or pharmacy personnel.

C. Taking into consideration the marking of the pages received by CVS as "2/6," "3/6," "4/6," and "5/6", L.A.'s reported epilepsy diagnosis, and L.A.'s specific request to fill her prescription for Tegretol, Pharmacist Reyes could have recognized that there might have been additional prescriptions requiring serialization and/or documentation and/or that the medications dispensed were not therapeutically appropriate to control L.A.'s epileptic seizures. Pharmacist Reyes failed to serialize and/or document the two additional pages that are alleged to have been faxed from Kaiser and failed to dispense L.A.'s prescription for Tegretol.

D. Based on the conduct as alleged, Pharmacist Reyes violated NAC 639.706 and/or engaged in unprofessional conduct as defined by NAC 639.945(1)(i).

E. As the pharmacy/pharmacy owner at which unprofessional conduct and violations of law are alleged by the Board to have occurred, Respondent CVS Pharmacy #9168 is legally responsible for those violations, including all errors and omissions of employee

Marilou Reyes and any other pharmacy personnel, and is subject to professional discipline pursuant to NRS 639.230(5), NAC 639.702, and/or NAC 639.945(3).

F. Respondent CVS had a duty to maintain a computerized system that has readily retrievable records and that has a procedure in place to ensure that recorded information is not deleted. NAC 639.910. Facsimile prescriptions must be maintained for at least two (2) years after receipt. NAC 639.711(5).

G. Respondent CVS's computer system did not maintain records of the facsimile pages from Kaiser marked "1/6" and "6/6". Kaiser records indicate that 7 prescriptions, including 2 duplicates, were sent to CVS and a notification of "success" was received following the transmission. CVS's system maintains deleted records for 24 hours locally and 30 days on the corporate level. CVS has identified no system record, transmission confirmation, audit trail, or other evidence showing that any additional prescriptions for L.A. were received and subsequently deleted.

H. Based on the violations as alleged, the Board may impose discipline against Respondent CVS # 9168 pursuant to NRS 639.210(12).

6. Those violations are pled with particularity in the Accusation and are grounds for action pursuant to NRS 639.210 and NRS 639.255.

7. To resolve this matter without incurring any further costs or the expense associated with a hearing and to avoid the uncertainty of a contested hearing, the Board and Respondent stipulate to the following penalties:

A. Respondent shall pay an administrative fine of **Six Thousand and 00/100 Dollars ($6,000.00)**, payable by *personal, business, certified or cashier's check, or money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before November 13, 2026.

B. Respondent shall pay the sum of **Six Hundred Fifty and 00/100 Dollars ($650.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in

investigating and prosecuting this matter. This sum shall be payable by *personal, business, certified or cashier's check, or money order* written to the "**Nevada State Board of Pharmacy.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before November 13, 2026.

C. Respondent acknowledges its duty to implement and maintain a system that retains all facsimile prescriptions received by CVS pharmacies for a period of no less than two (2) years from the date of receipt in accordance with NAC 639.711(5). On or before January 15, 2027, Respondent shall provide Board staff with written notification confirming its compliance with NAC 639.711(5), including a description of CVS's system, the policies or procedures governing the retention and retrieval of such fax prescriptions, and any changes made thereto as a result of this incident.

D. Respondent shall distribute a written communication to all CVS pharmacies reminding pharmacy personnel to carefully review facsimile prescriptions received by the pharmacy and, when questions arise concerning the quality, completeness, legibility, pagination, or accuracy of a facsimile transmission, to identify and contact the prescriber for clarification prior to processing or dispensing. On or before January 15, 2027, Respondent shall provide Board staff with written notification that such communication has been distributed.

8. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 24-010-PH-N. However, Respondent understands and acknowledges that its failure to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

9. The Board's General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 14, 2026, in Las Vegas, Nevada. Respondent will appear in person or through counsel at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear for the meeting.

10. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330, shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

11. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown, that might otherwise have been asserted by the Board on or before the effective date of this Order.

///

///

///

///

///

///

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 17th **day of** September **2026.**
CVS Pharmacy #9168

By: _____
Name: Leigh Parenteau
Title: Lead Director, Regulatory Affairs

Signed this 23rd **day of** September **2026.**
Nevada State Board of Pharmacy

By _____
AMY K. STEELMAN, ESQ.
General Counsel

DECISION AND ORDER

As to CVS Pharmacy #9168, in Case No. 24-010-PH-N, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this ____day of October, 2026.

Helen Park, President
Nevada State Board of Pharmacy

5B

FILED
JUL 2 1 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARILOU REYES, RPH,** **Certificate of Registration No. 11763,** **AND,** **CVS PHARMACY #9168,** **Pharmacy License No. PH00506,** **Respondents.**	**Case No. 24-010-RPH-N** **24-010-PH-N** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent Marilou Reyes ("Respondent Reyes"), because Respondent Reyes holds a certificate of registration issued by the Board pursuant to NRS 639.127, authorizing her to engage in the practice of pharmacy in the state of Nevada.

2. The Board has jurisdiction over CVS Pharmacy #9168 ("Respondent CVS" or "CVS"), because Respondent holds a license issued by the Board pursuant to NRS 639.230, authorizing Respondent CVS to operate a pharmacy located at 1119 California Ave., Reno, Nevada 90523.

FACTUAL ALLEGATIONS

3. On November 21, 2023, at approximately 9 a.m., patient L.A., a California resident, requested that prescriptions maintained by Kaiser Permanente Pharmacy in Los Angeles,

California ("Kaiser") be transferred on an emergency basis to CVS while she was visiting her sister in Reno.

4. While at CVS, L.A. informed two pharmaceutical technicians that she has epilepsy, had traveled without her medications, and needed an immediate transfer of her anti-seizure medication, Tegretol.

5. CVS technicians refused to contact Kaiser regarding the transfer request and informed L.A. that she should seek assistance from another, less busy, pharmacy.

6. L.A. remained at CVS and contacted Kaiser herself to initiate the transfer request.

7. Subsequently, Kaiser transferred, by way of facsimile, all of L.A.'s active prescriptions, totaling seven (7), two (2) of which were additional re-fills. The transferred medications included Tegretol, Metoprolol, Gabapentin, Levothyroxine (with additional re-fill), and Fluoxetine (with additional re-fill).

8. Respondent Reyes communicated directly with the Kaiser pharmacist regarding the transfer and accepted the facsimile transmission of the transferred prescriptions.

9. Kaiser records documented the successful facsimile transmission of all seven (7) transferred prescriptions to CVS. Kaiser also facsimiled detailed notes for each prescription, including the medication name, strength, quantity, and supply.

10. CVS utilizes an electronic facsimile system. All incoming facsimiles are initially placed in a queue pending retrieval by pharmacy staff. Once retrieved, the facsimile is printed and scanned, and the prescription information is then manually entered into CVS's pharmacy system.

11. CVS Pharmaceutical technician Shirley Donnelly only entered five (5) of L.A.'s seven (7) facsimiled prescriptions into its system and assigned prescription numbers for Gabapentin, Levothyroxine, Fluoxetine (with additional refill), and Metoprolol. Respondent Reyes verified the five (5) prescriptions.

12. While waiting for her prescription to be dispensed by CVS, L.A.'s condition deteriorated, and she became unable to effectively communicate.

13. After learning of L.A.'s condition during a telephone call with her, L.A.'s sister went to CVS at approximately 1:00 p.m. where she observed L.A. slumped over in a chair near the pharmacy counter unable to speak or otherwise communicate.

14. Shortly thereafter, a CVS employee dispensed Gabapentin, Levothyroxine, Fluoxetin, and Metoprolol to L.A.'s sister who immediately gave L.A. the medication while still in the pharmacy.

15. Later that day, L.A. experienced a seizure and was transported to Renown hospital by paramedics. The paramedics confirmed that none of the medications dispensed to Respondent earlier that day were to treat seizures.

16. During L.A.'s hospitalization, she experienced status epilepticus (continuous seizures), was admitted to the intensive care unit, and placed on a ventilator. She remained hospitalized from November 21, 2023 through November 24, 2023.

17. Following her discharge, L.A. experienced memory loss and was ordered to stop driving for six months.

18. Kaiser records reflect that L.A.'s Tegretol prescription had been transferred to Respondent CVS, while Respondent CVS records reflect no prescription for Tegretol.

19. The facsimile records maintained by CVS consisted of scanned pages marked "2/6," "3/6," "4/6", and "5/6." CVS did not maintain records of the pages marked "1/6" and "6/6", and Respondent CVS was unable to account for the missing pages or determine their contents.

20. CVS was further unable to retrieve the original transmission because facsimiles are immediately deleted from the system after they are entered into CVS's records. Pursuant to CVS's computer system, deleted facsimiles are moved to the "Delete Triage" and are only recoverable that same day.

21. CVS Corporate can only retrieve deleted records within 30 days of being sent to the "Deleted Triage."

PRIOR DISCIPLINE

22. In 1998, the Board disciplined Respondent CVS for a dispensing error and imposed a $400 fine.

23. In 2010, the Board disciplined Respondent CVS for a dispensing error and imposed a $1,000 fine.

24. In 2010, the Board disciplined Respondent CVS for mislabeling a prescription's directions, resulting in patient harm. The Board imposed a $750 fine.

APPLICABLE LAW

25. A pharmacist has a duty to review a patient's record before dispensing a prescription to determine its therapeutic appropriateness. NAC 639.707(4). The pharmacist may consider, among other things, diseases which the patient has.

26. A pharmacist has a duty to keep facsimile prescriptions for at least two (2) years after receipt. If the paper is not of sufficient quality to last for at least 2 years, the facsimile prescription must be reproduced on permanent paper, or the pharmacist must reduce the prescription to writing and attach the original transmission of the prescription to the reproduced copy or the prescription reduced to writing. NAC 639.711(5).

27. A pharmacist who receives a prescription to fill, including a prescription that is written, transcribed from an oral order or transferred to the pharmacy, shall mark on the prescription a unique serial number issued for that prescription. NAC 639.706(1).

28. A pharmacist shall maintain a physical record in the files of prescriptions that accurately explains or accounts for any serial number issued for a prescription that is not filled, including a serial number issued in error or for a prescription that is later rendered void. NAC 639.706(3).

29. A person who is issued a license to conduct a pharmacy shall ensure that the pharmacy uses a computerized system for recording information concerning prescriptions. NAC 639.924.

30. Any computerized system used by a pharmacy for recording information concerning prescriptions must be designed in such a manner that it provides a readily retrievable printed record of the information relating to a prescription or a patient which the pharmacy is required to maintain pursuant to state or federal law, including, without limitation, information relating to the original prescription or the refill or modification of that prescription. NAC 639.910(1)(a).

31. Any computerized system used by a pharmacy for recording information concerning prescriptions must be designed in such a manner that it provides a procedure that may be conducted at least once each day to ensure that the information which is recorded in the system is not lost or destroyed. NAC 639.910(1)(m).

32. Unprofessional conduct by a pharmacist includes, "performing any of his or her duties . . . in an incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

33. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

34. The Board may discipline a licensee who has violated any provisions of a regulation relating to the practice of pharmacy. NRS 639.210(12).

35. In lieu of, or in addition to, revoking or suspending a license holder's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

\\\

\\\

\\\

\\\

\\\

\\\

COUNT ONE
Unprofessional Conduct – Failure to Exercise Professional Judgment
(Respondents Reyes and CVS)

36. As alleged above, Respondent Reyes verified and dispensed only five (5) of L.A.'s seven (7) facsimile prescriptions, failing to verify and dispense, among others, L.A.'s prescription for Tegretol.

37. Respondent Reyes failed to locate L.A.'s prescription for Tegretol despite pharmacy staff being aware of L.A.'s epilepsy diagnosis and deteriorating condition near the pharmacy counter.

38. Based upon the foregoing, Respondent Reyes knew or reasonably should have known that L.A. was awaiting an anti-seizure medication, among others.

39. Respondent Reyes breached her duty under NAC 639.707(4) to evaluate whether the prescriptions that she had verified for L.A. were therapeutically appropriate to control L.A.'s epileptic seizures.

40. Had Respondent Reyes properly reviewed and considered L.A.'s known diagnosis of epilepsy and deteriorating condition when determining the therapeutic appropriateness of dispensing drugs that did not include an anti-seizure medication, Respondent Reyes likely would have discovered the omission to fill L.A.'s prescription for Tegretol.

41. As alleged above, Respondent Reyes performed her duties as a pharmacist in a negligent, unskillful or incompetent manner, thus engaging in unprofessional conduct.

42. As the owner/operator of the pharmacy at which Respondent Reyes was employed, Respondent CVS is responsible for Respondent Reyes' conduct as alleged above. Accordingly, the Board may discipline Respondent CVS pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

COUNT TWO
Unprofessional Conduct – Failure to Properly Serialize Prescriptions and/or Maintain Prescription Records Transmitted Via Facsimile (Respondents Reyes and CVS)

43. As the CVS pharmacist on duty on November 21, 2023, Respondent Reyes had a duty to assign unique serial numbers to each of the prescriptions transferred from Kaiser on behalf of L.A.

44. As the CVS pharmacist on duty on November 21, 2023, Respondent Reyes had a duty to generate a record or summary explaining or accounting for any serial numbers issued for prescriptions that were not filled by CVS for L.A.

45. As the CVS pharmacist on duty on November 21, 2023, Respondent Reyes had a duty to generate a record or summary documenting all the pertinent prescription information transferred from Kaiser on behalf of L.A.

46. Based upon the prescription information received from Kaiser, Respondent Reyes knew or reasonably should have known that there were seven (7) prescriptions requiring serialization and/or documentation. Respondent Reyes failed to serialize and/or document two of those prescriptions.

47. Given that L.A. was visibly distressed within the pharmacy, Respondent Reyes knew or reasonably should have known that it was critically important to fully and accurately serialize and document the prescriptions transferred from Kaiser on behalf of L.A.

48. By failing to fully and accurately serialize and document the prescriptions transferred from Kaiser on behalf of L.A., Respondent Reyes performed her duties as a pharmacist in a negligent, unskillful or incompetent manner, thus engaging in unprofessional conduct. NRS 639.210(4). See also NAC 639.945(1)(i).

49. As the owner/operator of the pharmacy at which Respondent Reyes was employed, Respondent CVS is responsible for Respondent Reyes' unprofessional conduct as alleged above. Accordingly, the Board may discipline Respondent CVS pursuant to NRS 639.230(5), NAC 639.702 and NAC 639.945(2).

COUNT THREE
Unprofessional Conduct – Failure to Maintain a Compliant Computerized System (Respondent CVS)

50. Respondent CVS had a duty to maintain a computerized system that has readily retrievable records and that has a procedure in place to ensure that recorded information is not deleted. NAC 639.910.

51. Respondent CVS performed its duties in an incompetent, unskillful, or negligent manner because it did not have a procedure in place to ensure that its original incoming facsimiles are readily retrievable. *See* NAC 639.910(1)(m); NAC 639.945(1)(i).

52. Having engaged in unprofessional conduct as alleged above, Respondent CVS is subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration for Respondent CVS Pharmacy #9168 and Respondent Reyes.

DATED this 21st day of July 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARILOU REYES, RPH,** **Certificate of Registration, No. 11763,** **Respondent.**	**Case No. 24-010-RPH-N** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, September 2, 2026, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hyatt Place
1790 E Plumb Ln
Reno, NV 89502

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Amy Steelman, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **aksteelman@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 21st day of JULY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARILOU REYES, RPH,** **Certificate of Registration, No. 11763,** **Respondent.**	**Case No. 24-010-RPH-N** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

MARILOU REYES, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 22nd day of July 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Marilou Reyes, RPh
[redacted]
Reno, NV [redacted]

Marilou Reyes, RPh
c/o CVS Pharmacy #9168
1119 California Ave.
Reno, NV 89509

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARILOU REYES, RPH,** **Certificate of Registration No. 11763, and** **CVS PHARMACY #9168,** **Pharmacy License No. PH00506,** **Respondents.**	**Case Nos. 24-010-RPH-N** **24-010-PH-N** **STIPULATION AND ORDER** **[MARILOU REYES ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy ("Board"), by and through counsel, Amy K. Steelman, Esq., and Marilou Reyes, RPh, Certificate of Registration No. 11763, ("Respondent"), **HEREBY STIPULATE AND AGREE THAT:**

1. On or about July 27, 2026, Respondent was served with the Notice of Intended Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

2. Respondent is fully aware of the right to seek the advice of counsel in this matter prior to entering into this Stipulation.

3. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal, and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

4. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing, reconsideration, appeal, and any and all other rights related to this action that may be accorded by the

Nevada Administrative Procedure Act, Administrative Procedure Before Certain Regulatory Bodies, and the Nevada Pharmacy Act.

5. Respondent contests the allegations stated in Count One and Count Two of the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein. This Stipulation shall not be construed as an admission of liability by Respondent nor a concession by the Board that the Accusation is not based upon sufficient evidence.

A. Respondent verified and dispensed four facsimile prescriptions for patient L.A.

B. Kaiser reported that additional prescriptions, including L.A.'s prescription for Tegretol, were also faxed; CVS disputes that any additional prescriptions for L.A. were received. CVS contends that there is a lack of evidence that any additional prescriptions were successfully transmitted to or received by CVS, cntered into any CVS system, or subsequently deleted by CVS or pharmacy personnel.

C. Taking into consideration the marking of the pages received by CVS as "2/6," "3/6," "4/6," and "5/6", L.A.'s reported epilepsy diagnosis, and L.A.'s specific request to fill her prescription for Tegretol, Respondent could have recognized that there might have been additional prescriptions requiring serialization and/or documentation and/or that the medications dispensed were not therapeutically appropriate to control L.A.'s epileptic seizures. Respondent failed to serialize and/or document the two additional pages that are alleged to have been faxed from Kaiser and failed to dispense L.A.'s prescription for Tegretol.

D. Based on the conduct as alleged, Respondent violated NAC 639.706 and/or engaged in unprofessional conduct as defined by NAC 639.945(1)(i) and is subject to discipline pursuant to NRS 639.210(4) and/or NRS 639.210(12).

6. Those violations are pled with particularity in the Accusation and are grounds for action pursuant to NRS 639.210 and NRS 639.255.

7. To resolve this matter without incurring any further costs or the expenses associated with a hearing and to avoid the uncertainty of a contested hearing, the Board and Respondent stipulate to the following penalties:

A. Respondent shall pay an administrative fine of **Four Thousand and 00/100 Dollars ($4,000.00)**, payable by *personal, business, certified, or cashier's check* or *money order* written to the **"State of Nevada, Office of the Treasurer."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before November 13, 2026.

B. Respondent shall pay the sum of **Six Hundred Fifty and 00/100 Dollars ($650.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *personal, business, certified, or cashier's check* or *money order* written to the **"Nevada State Board of Pharmacy."** Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, on or before November 13, 2026.

8. This Stipulation constitutes a full and final resolution of the Accusation in Case No. 24-010-RPH-N. However, Respondent understands and acknowledges that her failure to comply with the terms stated herein may result in issuance by the Executive Secretary of an order to show cause, pursuant to NAC 639.965, directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation by Respondent, the Board may impose additional discipline not inconsistent with the provisions of NRS Chapter 639.

9. The Board's General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 14, 2026, in Las Vegas, Nevada. Respondent will appear in person or through counsel at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent fails to appear for the meeting.

10. The Board may accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330, shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

11. If the Board rejects any part or all this Stipulation, and unless the parties reach an alternative agreement on the record during the hearing, the parties agree that the Board may hear a full contested hearing on the merits of all alleged violations as stated in the Accusation. The terms and admissions herein may not be used, relied upon, or referred to by any party during any such hearing.

12. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any or all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have been asserted by the Board on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 21st **day of** Sept **2026.**

By Marilou A-Reyes

MARILOU REYES, RPH
Certificate of Registration No. 11763

Signed this 22nd **day of** Sept **2026.**
Nevada State Board of Pharmacy

By Amy K Steelman

AMY K. STEELMAN, ESQ.
General Counsel

DECISION AND ORDER

As to Marilou Reyes, in Case No. 24-010-RPH-N, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this ____day of October, 2026.

Helen Park, President
Nevada State Board of Pharmacy

5C

FILED
SEP 15 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **QUALITY COMPOUNDING RX OF AMERICA, License No. PH02986,** **Respondent.**	**CASE NO. 25-253-PH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because Quality Compounding Rx of America (Respondent) holds a pharmacy license issued by the Board, Pharmacy License No. PH02986.

FACTUAL ALLEGATIONS

2. On or about August 1, 2013, Respondent was initially licensed by the Board to dispense dangerous drugs and controlled substances to patients in Nevada. In July 2026, Respondent submitted to the Board an application for ownership change.

3. Respondent is a 503A pharmacy that dispenses sterile compounded drug products to patients in Nevada as the term compound is defined at NRS 639.0053. Respondent's practice is governed by NRS Chapters 453, 454, and 639, and by Section 503A of the federal Food, Drug and Cosmetic Act (FD&C Act).

4. A Board investigation found that, between at least April 22, 2025, and September 11, 2025, Respondent distributed or dispensed hundreds of compounded semaglutide prescriptions and compounded tirzepatide prescriptions to Nevada patients. These drugs are essentially copies

of commercially available drug products manufactured under the brand names Ozempic, Wegovy, Mounjaro, and/or Zepbound.

5. Board investigators reviewed the documentation for a sample of ten (10) compounded semaglutide prescriptions and ten (10) compounded tirzepatide prescriptions Respondent distributed or dispensed in Nevada. Of these prescriptions, only four (4) contained a clear statement of material difference from the prescribing practitioner attesting to a patient-specific need for a compounded variation of the commercially available drug product.

6. None of the compounded semaglutide or tirzepatide prescriptions Respondent distributed or dispensed in Nevada contained a drug or an active pharmaceutical ingredient that appeared on the FDA's shortage list at the time of dispensing or distribution.

7. The compounded semaglutide and tirzepatide drug products Respondent distributed or dispensed in Nevada were packaged in a container and with a label branded with "Quality Compounding Rx of America."

8. Respondent distributed the compounded semaglutide and tirzepatide drug products in interstate commerce.

APPLICABLE LAW

9. The Board may revoke the license or registration of any licensee or registrant who has violated any provision of the FD&C Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

10. Generally, if a compounding pharmacy wishes to produce a drug in a manner that does not comply with section 503A of the FD&C Act, it must submit a new drug application pursuant to section 505 of the FD&C Act. *See* 21 U.S.C. § 355.

11. To comply with section 503A of the FD&C Act, a compounding pharmacy may not "compound regularly or in inordinate amounts . . . any drug products that are essentially copies of a commercially available drug product." 21 U.S.C. § 353a(b)(1)(D). Drug products are not essentially copies if "there is a change, made for an identified individual patient, which produces

for that patient a significant difference, *as determined by the prescribing practitioner*, between the compounded drug and the comparable commercially available drug product." 21 U.S.C. § 353a(b)(2) (emphasis added).

12. The FDA has published guidance concerning compounded drug products that are essentially copies of commercially available drugs. *See Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry*, 83 Fed. Reg. 2790 (January 19, 2018); *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry*, 83 Fed. Reg. 2786 (January 18, 2018). This guidance sets forth the generally accepted standard of care that a compounding pharmacy must adhere to when producing compounded drug products with pharmacological properties that mimic those of commercially available drugs.

13. Under section 502 of the FD&C Act, a drug is misbranded if it bears a false or misleading label or is packaged in a container suggesting that it is proprietary to the seller when it is, in fact, an imitation of some other manufacturer's patented drug product. 21 U.S.C. § 352(i).

14. Under section 301 of the FD&C Act, it is unlawful to distribute a misbranded drug in interstate commerce. *See* 21 U.S.C. § 335.

15. The Board may revoke or suspend the license or registration of any licensee or registrant who has engaged in unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

16. It is unprofessional conduct and/or contrary to the public interest for a pharmacy to compound or dispense or permit to be compounded or dispensed substandard drug products. NAC 639.945(1)(a).

17. It is unprofessional conduct and/or contrary to the public interest for a pharmacy to perform or in any way be a party to any fraudulent or deceitful practice or transaction. NAC 639.945(1)(h).

COUNT ONE

Violations of Sections 301, 502, and 505 of the FD&C Act

18. As alleged above, Respondent produced and dispensed compounded drug products that were essentially copies of commercially available drug products manufactured under the brand names Ozempic, Wegovy, Mounjaro, and/or Zepbound.

19. Respondent failed to document a shortage of said commercially available drugs and/or, in some cases, failed to document a specific patient need for some compounded variation thereof in accordance with FDA guidance.

20. Respondent routinely affixed patient-specific labels to product containers even when the formulations for the drugs were not developed pursuant to a statement of significant different issued by the prescribing practitioner.

21. The patient-specific labels were a subterfuge intended to avoid the requirement to file a new drug application pursuant to section 505 of the FD&C Act and/or to conceal the fact that the sterile compounds were essentially copies of commercially available drug products manufactured under the brand names Ozempic, Wegovy, Mounjaro, and/or Zepbound.

22. By producing and dispensing the sterile compounds in the manner described above, Respondent distributed "misbranded" drugs within the meaning of section 502 of the FD&C Act. *See* 21 U.S.C. § 352(i).

23. By distributing misbranded products in interstate commerce, Respondent violated section 301 of the FD&C. *See* 21 U.S.C. § 331.

24. Respondent produced copies of commercially available drugs in a manner requiring the submission of a new drug application pursuant to section 505 of the FD&C Act.

25. By failing to submit a new drug application to the FDA as required by section 505 of the FD&C, Respondent violated section 505 of the FD&C Act.

26. Based on the foregoing, the Board may discipline Respondent pursuant to NRS 639.210(11) for violating the FD&C Act.

COUNT TWO
Unprofessional Conduct

27. As alleged above, Respondent produced and dispensed sterile compounded drug products that were essentially copies of commercially available drug products manufactured under the brand names Ozempic, Wegovy, Mounjaro, and/or Zepbound.

28. Respondent failed to adhere to applicable FDA guidance when it produced drug products that were essentially copies of commercially available drug products. As a result, Respondent compounded and dispensed substandard drug products, which is unprofessional conduct as defined by NAC 639.945(1)(a).

29. Respondent marketed and packaged its sterile compounds in a manner intended to conceal the fact that its compounds were essentially copies of commercially available drug products. In so doing, Respondent engaged in deceitful practices, which is unprofessional conduct as defined by NAC 639.945(1)(h).

30. Based on the foregoing, the Board may discipline Respondent for unprofessional conduct pursuant to NRS 639.210(4).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license of Quality Compounding Rx of America.

DATED this 15th day of September 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **QUALITY COMPOUNDING RX OF AMERICA, License No. PH02986,** **Respondent.**	**Case No. 25-253-PH_S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Amy K. Steelman, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **aksteelman@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 15th day of SEPTEMBER 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **QUALITY COMPOUNDING RX OF AMERICA, License No. PH02986,** **Respondent.**	**Case No. 25-253-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

AUTHORIZED REPRESENTATIVE FOR QUALITY COMPOUNDING RX OF AMERICA

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 15th day of September 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Quality Compounding Rx of America
801 S Rancho Dr, #E7
Las Vegas, NV 89106

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

5D

FILED
SEP 09 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DAVID M. SNIPPER, M.D.,** **Certificate of Registration No. CS33549,** **Respondent.**	**Case No. 25-382-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, David M. Snipper, M.D. ("Respondent") held a controlled substance registration issued by the Board, Certificate of Registration No. CS33549.

FACTUAL ALLEGATIONS

2. Respondent was licensed by the Nevada State Board of Medical Examiners ("Medical Board") as a medical doctor, specializing in anesthesiology, until December 12, 2025.

3. Pursuant to a Settlement Agreement and Order in the Medical Board's Case No. 25-8772-2 ("SAO"), approved on December 12, 2025, Respondent voluntarily surrendered his license with the Medical Board. The SAO included a provision that Respondent will not apply for reinstatement of his license for a period of one year from the effective date of the SAO.

4. According to the terms of the SAO, Respondent admitted that he knowingly and willfully failed to comply with a Medical Board order in violation of NRS 630.3065(2)(a).

5. Specifically, the Medical Board directed Respondent to undergo an observed urine and hair drug test related to concerns that he was under the influence of illegal drugs. Respondent failed to complete the required drug screening in the time provided in the Medical Board's order.

6. The SAO was supported by reasonable evidence, including documentation and witness statements.

7. On or about September 25, 2025, after learning that Respondent's medical license had been suspended pending investigation, the Board placed Respondent's certificate of registration to prescribe controlled substances on concurrent suspension pursuant to NRS 639.2107.

8. On or about October 21, 2025, Respondent signed a surrender for cause of his Drug Enforcement Administration certificate of registration.

APPLICABLE LAW

9. The Board may revoke or suspend the registration to prescribe controlled substances of any practitioner whose federal registration to dispense controlled substances has been surrendered, suspended, or revoked. NRS 453.236(1)(c); NRS 639.2107.

10. The Board may suspend the registration of any practitioner whose license has been surrendered to or revoked or suspended by another licensing board. NRS 639.2107.

11. The Board may revoke or suspend the registration of any practitioner who is guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4); NRS 453.236(1)(e); NRS 453.231(1)(h).

\\\

\\\

\\\

\\\

\\\

COUNT ONE

Failure to Maintain Drug Enforcement Administration Registration

12. As alleged above, by agreeing to surrender his Drug Enforcement Administration registration for cause, Respondent has failed to maintain his required federal registration to dispense controlled substances and is subject to discipline pursuant to NRS 453.236(1)(c) and NRS 639.2107.

COUNT TWO

Unprofessional Conduct – Failure to Comply with Licensing Board

13. As alleged above, by violating NRS 630.3065(2)(a) as detailed in the Medical Board's SAO in Case No. 25-8772-2, Respondent has behaved in an unprofessional manner and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.231(1)(h), NRS 639.210(4), and/or NRS 639.2107.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of David M. Snipper.

DATED this 9th day of SEPTEMBER 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DAVID M. SNIPPER, M.D.,** **Certificate of Registration No. CS33549,** **Respondent.**	**Case No. 25-382-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Amy Steelman, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **aksteelman@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of SEPTEMBER 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DAVID M. SNIPPER, M.D.,** **Certificate of Registration No. CS33549,** **Respondent.**	**Case No. 25-382-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

DAVID M. SNIPPER, M.D.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of September 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail Standard U.S. mail to the following:

David Snipper, M.D.
c/o Excellyon Clinic
7470 S Dean Martin Dr #101
Las Vegas, NV 89139

David Snipper, M.D.
[redacted]
Las Vegas, NV [redacted]

David Snipper, M.D.
[redacted]
Las Vegas, NV [redacted]

David Snipper, M.D.
[redacted]
Las Vegas, NV [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

5E

FILED
SEP 30 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LAS VEGAS COMMUNITY PHARMACY, Pharmacy License No. PH04396,** **NATALIE NHU NGUYEN, RPH, Certificate of Registration No. 18735, and** **ALI MACINTOSH, PT Certificate of Registration No. PT26920,** **Respondents.**	**CASE NOS. 24-133-PH-S** **24-133-RPH-S** **24-133-PT-S** **FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the events alleged herein, Respondent Las Vegas Community Pharmacy, License No. PH04396, was a pharmacy licensed by the Board, Natalie Nhu Nguyen, RPh (Nguyen), Certificate of Registration No. 18735, was a pharmacist registered with the Board, and Ali Macintosh, PT (Macintosh), Certificate of Registration No. PT26920, was a pharmaceutical technician registered with the Board.

FACTUAL ALLEGATIONS

2. Macintosh owned Las Vegas Community Pharmacy at the time of the events alleged herein.

3. Nguyen was employed as managing pharmacist by Las Vegas Community Pharmacy from August 31, 2023, until approximately October 14, 2024; however, Nguyen was

employed on a part-time basis and not on duty in the pharmacy and active in the management of the pharmacy full-time.

4. On or about April 10, 2024, an annual inspection of Las Vegas Community Pharmacy revealed evidence in the form of supplier invoices and shipping confirmations that the pharmacy purchased drug products through MatchRX.

5. MatchRX, located in Michigan, is not licensed to engage in business as a wholesaler in Nevada.

6. Macintosh placed the orders with MatchRX in Nguyen's absence.

7. On or about October 10, 2024, the Board issued and served upon MatchRX an Order to Cease-and-Desist together with Citation and Fine for unlicensed wholesale distribution into Nevada.

APPLICABLE LAW

8. The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54), enacted by Congress on November 27, 2013, added Section 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 582 of the FD&C Act (21 U.S.C. § 360eee-1) establishes the requirements that certain entities in the pharmaceutical distribution supply chain, including pharmacies, must follow related to product tracing, verification, and authorized trading partners. Failure to comply is a prohibited act under 21 U.S.C. § 331(t).

9. Any person who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license pursuant to the provisions of NRS Chapter 639. NRS 639.100; NRS 639.233(1). Engaging in the business of wholesale distribution without a license is a felony. NRS 639.100(2).

10. Every wholesale distributor who engages in wholesale distributions of prescription drugs in interstate commerce must be licensed by the state into which the drug is distributed. 21 U.S.C. § 353(e)(1)(A); 21 CFR § 205.4.

11. Purchasing a drug from an unlicensed wholesaler does not constitute a bona fide transaction. NRS 639.595.

12. Performing any duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

13. Aiding or abetting a person not licensed in the State of Nevada constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

14. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(11).

15. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any issued by the Board. NRS 639.210(12).

16. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.210(12) and (15); NRS 639.220(1); NAC 639.702.

17. A managing pharmacist shall be on duty in the pharmacy and active in the management of the pharmacy full-time. NRS 639.220(3)(b).

18. A managing pharmacist of a pharmacy shall be responsible for, and must have knowledge and control of, the acquisition and disposition by the pharmacy of the stock of the pharmacy and shall ensure that the records relating to the acquisition or disposition of the stock of the pharmacy are maintained as required by law. NAC 639.510(2).

19. A pharmaceutical technician may only performs those functions permitted by law. NRS 639.1371(5); NAC 639.245; NAC 639.700; NAC 639.702.

20. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violation of Federal Law - Aiding and Abetting Unlicensed Wholesale Distribution

21. By purchasing drug products through MatchRX, a company not licensed to engage in the business of wholesale distribution into Nevada, Respondents, and each of them, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 360eee-1, 21 U.S.C. § 331(t), 21 U.S.C. § 353(e)(1)(A) and/or 21 CFR Part 205, and are subject to discipline pursuant to NRS 639.210(11).

COUNT TWO

Violation of State Law - Aiding and Abetting Unlicensed Wholesale Distribution

22. By purchasing drug products through MatchRX, a company not licensed to engage in the business of wholesale distribution into Nevada, Respondents, and each of them, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.100, NRS 639.233(1) and/or NRS 639.595, and are subject to discipline pursuant to NRS 639.210(12).

COUNT THREE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

23. By their actions as alleged herein, Respondents, and each of them, performed their respective duties in an incompetent, unskillful or negligent manner, engaged in unprofessional conduct as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 639.210(4).

COUNT FOUR

Unprofessional Conduct – Aiding and Abetting Unlicensed Wholesale Distribution

24. By purchasing drug products through MatchRX, a company not licensed to engage in the business of wholesale distribution into Nevada, Respondents, and each of them, aided and abetted unlicensed wholesale distribution, engaged in unprofessional conduct as defined in NAC 639.945(1)((j), and are subject to discipline pursuant to NRS 639.210(4).

COUNT FIVE

Violation of State Law –Managing Pharmacist Serving on Part-Time Basis

25. By employing Nguyen as a managing pharmacist on a part-time basis, who was not on duty in the pharmacy and active in the management of the pharmacy full-time, Respondents, and each of them, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.220(3)(b), and are subject to discipline pursuant to NRS 639.210(12).

COUNT SIX

Violation of State Law –Acquisition of Pharmacy Stock by Unauthorized Personnel

26. By permitting Macintosh as a pharmaceutical technician to place orders for pharmacy stock in Nguyen's absence, Respondents, and each of them, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.1371(5), NAC 639.245, NAC 639.510(2), NAC 639.700 and/or NAC 639.702, and are subject to discipline pursuant to NRS 639.210(12).

COUNT SEVEN

Managing Pharmacist Responsibility

(Respondent Nguyen)

27. As the managing pharmacist of Las Vegas Community Pharmacy at the time of the violations of law as alleged herein, Nguyen is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

COUNT EIGHT

Pharmacy/Pharmacy Owner Responsibility

(Respondents Las Vegas Community Pharmacy and Macintosh)

28. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondents Las Vegas Community Pharmacy and Macintosh are responsible for those violations and subject to discipline pursuant to NRS 639.210, NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to pharmacy license and registrations of these respondents.

Signed this 30th day of September 2025.

Yenh Long, Pharm.D.,
Deputy Executive Secretary of the Nevada State Board of Pharmacy,
for and on behalf of J. David Wuest, R.Ph.,
Executive Secretary of the
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LAS VEGAS COMMUNITY PHARMACY, Pharmacy License No. PH04396,** **Respondent.**	**CASE NO. 24-133-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a First Amended Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 30th day of September 2025.

Yenh Long, Pharm.D.,
Deputy Executive Secretary of the Nevada State Board of Pharmacy,
for and on behalf of J. David Wuest, R.Ph.,
Executive Secretary of the
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LAS VEGAS COMMUNITY PHARMACY, Pharmacy License No. PH04396,** **Respondent.**	**CASE NO. 24-133-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the First Amended Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the First Amended Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the First Amended Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR
Las Vegas Community Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 30th day of September 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Las Vegas Community Pharmacy
3200 N Soaring Gulls Dr., Suite 101
Las Vegas, NV 89129

Natalie Nguyen, RPh
[redacted]
Las Vegas, NV [redacted]

QHR Pharmacy
c/o Natalie Nguyen, RPh
3375 E Russell Rd 1G
Las Vegas, NV 89120

Ali Macintosh, PT
[redacted]
Las Vegas, NV [redacted]

Evergreen Pharmacy
c/o Ali Macintosh, PT
[redacted]
Las Vegas, NV [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
JUL 25 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LAS VEGAS COMMUNITY PHARMACY, Pharmacy License No. PH04396,** **Respondent.**	**CASE NO. 24-133-PH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the events alleged herein, Respondent Las Vegas Community Pharmacy, License No. PH04396, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. On or about April 10, 2024, an annual inspection of Las Vegas Community Pharmacy revealed evidence in the form of supplier invoices and shipping confirmations that Respondent purchased drug products through MatchRX.

3. MatchRX, located in Michigan, is not licensed to engage in business as a wholesaler in Nevada.

4. On or about October 10, 2024, the Board issued and served upon MatchRX an Order to Cease-and-Desist together with Citation and Fine for unlicensed wholesale distribution into Nevada.

APPLICABLE LAW

5. The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54), enacted by Congress on November 27, 2013, added Section 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 582 of the FD&C Act (21 U.S.C. § 360eee-1) establishes the requirements that certain entities in the pharmaceutical distribution supply chain, including pharmacies, must follow related to product tracing, verification, and authorized trading partners. Failure to comply is a prohibited act under 21 U.S.C. § 331(t).

6. Any person who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license pursuant to the provisions of NRS Chapter 639. NRS 639.100; NRS 639.233(1). Engaging in the business of wholesale distribution without a license is a felony. NRS 639.100(2).

7. Every wholesale distributor who engages in wholesale distributions of prescription drugs in interstate commerce must be licensed by the state into which the drug is distributed. 21 U.S.C. § 353(e)(1)(A); 21 CFR § 205.4.

8. Purchasing a drug from an unlicensed wholesaler does not constitute a bona fide transaction. NRS 639.595.

9. Performing any duties as the owner of a business or an entity licensed by the Board in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

10. Aiding or abetting a person not licensed in the State of Nevada constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

11. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(11).

12. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any issued by the Board. NRS 639.210(12).

13. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5). Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violation of Federal Law - Aiding and Abetting Unlicensed Wholesale Distribution

14. By purchasing drug products through MatchRX, a company not licensed to engage in the business of wholesale distribution into Nevada, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 360eee-1, 21 U.S.C. § 331(t), 21 U.S.C. § 353(e)(1)(A) and/or 21 CFR Part 205, and is subject to discipline pursuant to NRS 639.210(11).

COUNT TWO

Violation of State Law - Aiding and Abetting Unlicensed Wholesale Distribution

15. By purchasing drug products through MatchRX, a company not licensed to engage in the business of wholesale distribution into Nevada, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.100, NRS 639.233(1) and/or NRS 639.595, and is subject to discipline pursuant to NRS 639.210(12).

COUNT THREE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

16. By purchasing drug products through MatchRX, a company not licensed to engage in the business of wholesale distribution into Nevada, Respondent performed its duties as the owner of a pharmacy licensed by the Board in an incompetent, unskillful or negligent manner, engaged in unprofessional conduct as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 639.210(4), NRS 639.230(5) and/or NAC 639.945(3).

COUNT FOUR

Unprofessional Conduct – Aiding and Abetting Unlicensed Wholesale Distribution

17. By purchasing drug products through MatchRX, a company not licensed to engage in the business of wholesale distribution into Nevada, Respondent aided and abetted unlicensed wholesale distribution, engaged in unprofessional conduct as defined in NAC 639.945(1)((j), and is subject to discipline pursuant to NRS 639.210(4), NRS 639.230(5) and/or NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to pharmacy license of this Respondent.

Signed this 25th day of July 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LAS VEGAS COMMUNITY PHARMACY, Pharmacy License No. PH04396,** **Respondent.**	**CASE NO. 24-133-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 15, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 25th day of JULY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LAS VEGAS COMMUNITY PHARMACY, Pharmacy License No. PH04396,** **Respondent.**	**CASE NO. 24-133-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR
Las Vegas Community Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of July 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Las Vegas Community Pharmacy
3200 N Soaring Gulls Dr., Suite 101
Las Vegas, NV 89129

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
SEP 22 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, vs. LAS VEGAS COMMUNITY PHARMACY, Pharmacy License No. PH04396, Respondent.	Case No. 24-133-PH-S ANSWER AND NOTICE OF DEFENSE

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. **That Las Vegas Community Pharmacy's objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges, is hereby interposed on the following grounds:**

The allegations are not properly substantiated and attempt to include violation references to Acts, Policies, and Laws that pertain to the wholesale distributor and not to Respondent. Pursuant to 21 USC 360eee-1(d), Respondent maintains all records of traceability as required under the Code. The Notice refers to the wholesale distributor, MatchRx, who, unknowingly to Respondent, was allegedly not licensed to transact business in the state of Nevada. Respondent relied on statements from its vendor on proper licensing and, once contrary information was obtained from the Board of Pharmacy, as done in this situation, Respondent immediately ceased doing business with the vendor. In this case, the vendor's invoices and other communications implied DSCSA compliance. Respondent later learned of the licensing issue with MatchRx directly by a Board of Pharmacy inspector and, at that time, Respondent immediately ceased using MatchRx for any and all future orders.

Furthermore, in Nevada, any claim of attempt to violate, assist or abet in the violation of, or conspire to violate, requires the knowledge by the Respondent. *See* Ungaro v. Desert Palace, Inc. 732 F.Supp. 1522, 1533, n3 (D. Nev.1989). In this case, Respondent was, at the relevant times, not knowledgeable about the alleged licensing issue with MatchRx. Additionally, the Notice fails to establish the damage resulting from such act(s)—another requirement to justify a claim of assisting, aiding, abetting, and/or conspiracy. *Id.* As such, any attempt to penalize Respondent based on these allegations must be denied and/or rejected.

2. **That, in answer to the Notice of Intended Action and Accusation, Las Vegas Community Pharmacy admits, denies, and alleges as follows:**

A. I, Ali Macintosh, President of Las Vegus Community Pharmacy, Inc., dba Las Vegas Community Pharmacy (the "Respondent"), respectfully submit this Answer and Notice of Defense within 20 days of receipt of the Notice of Intended Action and Accusation (the "Notice"). I personally received the Notice on or around September 3, 2025 after returning from travels outside of the country.

B. On or about April 10, 2024, invoices and shipping confirmations were provided by the Respondent to a Board of Pharmacy inspector, as requested, including some related to purchases from MatchRx.

C. At the time of the April 2024 inspection, the inspector recommended that Respondent not buy products from MatchRX and purchase only from local sources. The inspector neither restricted nor properly explained the reason for this recommendation. In fact, the inspector noted "Good Inspection" on the final report—implying no significant wrongdoing.

D. The Respondent can neither confirm nor deny the main business location and/or Nevada licensing status of MatchRX.

E. The Respondent can neither confirm nor deny the October 2024 issuance of a Cease-and-Desist Order served upon MatchRX since, at that time, a copy of such issuance was not provided to Respondent.

F. On or about March 13, 2025, invoices and shipping confirmations were, again, provided by the Respondent to a Board of Pharmacy inspector, as requested, including some related to purchases from MatchRx.

G. At the time of the March 2025 inspection, the inspector advised Respondent that MatchRx is not properly licensed to sell products in Nevada. Once given this information, Respondent immediately ceased ordering any and all products from MatchRx.

H. Respondent admits the existence of the "Applicable Law" cited in the Notice, but denies its relevancy to the Respondent, as stated in Paragraph 1, above.

3. Respondent concludes that:

In regard to COUNT ONE, Respondent neither violated, attempted to violate, assisted or abetted in the violation of, nor conspired to violate 21 USC 360eee-1, 21 USC 331(t), 21 USC 353(e)(1)(A), and/or 21 CFR Part 205, because Respondent relied on vendor communication and lack of notice from the Board of Pharmacy inspector. As such, Respondent is not subject to discipline pursuant to NRS 639.210(11).

In regard to COUNT TWO, Respondent neither violated, attempted to violate, assisted or abetted in the violation of, nor conspired to violate NRS 639.100, NRS 639.233(1) and/or NRS 639.595, and is not subject to discipline pursuant to NRS 639.210(12).

In regard to COUNT THREE, Respondent performed its duties in a competent, skillful, and professional manner as defined in NAC 639.945(1)(i), and is not subject to discipline pursuant to NRS 639.210(4), NRS 639.230(5), and/or NAC 639.945(3).

In regard to COUNT FOUR, Respondent neither aided nor abetted unlicensed wholesale distribution and, as always, engaged in professional conduct as defined in NAC 639.945(1)j), and is not subject to discipline pursuant to NRS 639.210(4), NRS 639.230(5), and/or NAC 639.945(3).

Based on this Answer and Notice of Defense, any attempt to penalize Respondent based on the allegations in the Notice must be denied and/or rejected.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 22 day of September 2025.

RESPONDENT

Las Vegus Community Pharmacy, Inc.
dba Las Vegas Community Pharmacy
by: Ali Macintosh, President

5F

FILED
SEP 28 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LAS VEGAS COMMUNITY PHARMACY, Pharmacy License No. PH04396,** **NATALIE NHU NGUYEN, RPH, Certificate of Registration No. 18735, and** **ALI MACINTOSH, PT Certificate of Registration No. PT26920,** **Respondents.**	**CASE NOS. 24-133-PH-S** **24-133-RPH-S** **24-133-PT-S** **FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the events alleged herein, Respondent Las Vegas Community Pharmacy, License No. PH04396, was a pharmacy licensed by the Board, Natalie Nhu Nguyen, RPh (Nguyen), Certificate of Registration No. 18735, was a pharmacist registered with the Board, and Ali Macintosh, PT (Macintosh), Certificate of Registration No. PT26920, was a pharmaceutical technician registered with the Board.

FACTUAL ALLEGATIONS

2. Macintosh owned Las Vegas Community Pharmacy at the time of the events alleged herein.

3. Nguyen was employed as managing pharmacist by Las Vegas Community Pharmacy from August 31, 2023, until approximately October 14, 2024; however, Nguyen was

employed on a part-time basis and not on duty in the pharmacy and active in the management of the pharmacy full-time.

4. On or about April 10, 2024, an annual inspection of Las Vegas Community Pharmacy revealed evidence in the form of supplier invoices and shipping confirmations that the pharmacy purchased drug products through MatchRX.

5. MatchRX, located in Michigan, is not licensed to engage in business as a wholesaler in Nevada.

6. Macintosh placed the orders with MatchRX in Nguyen's absence.

7. On or about October 10, 2024, the Board issued and served upon MatchRX an Order to Cease-and-Desist together with Citation and Fine for unlicensed wholesale distribution into Nevada.

APPLICABLE LAW

8. The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54), enacted by Congress on November 27, 2013, added Section 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 582 of the FD&C Act (21 U.S.C. § 360eee-1) establishes the requirements that certain entities in the pharmaceutical distribution supply chain, including pharmacies, must follow related to product tracing, verification, and authorized trading partners. Failure to comply is a prohibited act under 21 U.S.C. § 331(t).

9. Any person who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license pursuant to the provisions of NRS Chapter 639. NRS 639.100; NRS 639.233(1). Engaging in the business of wholesale distribution without a license is a felony. NRS 639.100(2).

10. Every wholesale distributor who engages in wholesale distributions of prescription drugs in interstate commerce must be licensed by the state into which the drug is distributed. 21 U.S.C. § 353(e)(1)(A); 21 CFR § 205.4.

11. Purchasing a drug from an unlicensed wholesaler does not constitute a bona fide transaction. NRS 639.595.

12. Performing any duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

13. Aiding or abetting a person not licensed in the State of Nevada constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

14. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(11).

15. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any issued by the Board. NRS 639.210(12).

16. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.210(12) and (15); NRS 639.220(1); NAC 639.702.

17. A managing pharmacist shall be on duty in the pharmacy and active in the management of the pharmacy full-time. NRS 639.220(3)(b).

18. A managing pharmacist of a pharmacy shall be responsible for, and must have knowledge and control of, the acquisition and disposition by the pharmacy of the stock of the pharmacy and shall ensure that the records relating to the acquisition or disposition of the stock of the pharmacy are maintained as required by law. NAC 639.510(2).

19. A pharmaceutical technician may only performs those functions permitted by law. NRS 639.1371(5); NAC 639.245; NAC 639.700; NAC 639.702.

20. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violation of Federal Law - Aiding and Abetting Unlicensed Wholesale Distribution

21. By purchasing drug products through MatchRX, a company not licensed to engage in the business of wholesale distribution into Nevada, Respondents, and each of them, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 360eee-1, 21 U.S.C. § 331(t), 21 U.S.C. § 353(e)(1)(A) and/or 21 CFR Part 205, and are subject to discipline pursuant to NRS 639.210(11).

COUNT TWO

Violation of State Law - Aiding and Abetting Unlicensed Wholesale Distribution

22. By purchasing drug products through MatchRX, a company not licensed to engage in the business of wholesale distribution into Nevada, Respondents, and each of them, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.100, NRS 639.233(1) and/or NRS 639.595, and are subject to discipline pursuant to NRS 639.210(12).

COUNT THREE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

23. By their actions as alleged herein, Respondents, and each of them, performed their respective duties in an incompetent, unskillful or negligent manner, engaged in unprofessional conduct as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 639.210(4).

COUNT FOUR

Unprofessional Conduct – Aiding and Abetting Unlicensed Wholesale Distribution

24. By purchasing drug products through MatchRX, a company not licensed to engage in the business of wholesale distribution into Nevada, Respondents, and each of them, aided and abetted unlicensed wholesale distribution, engaged in unprofessional conduct as defined in NAC 639.945(1)((j), and are subject to discipline pursuant to NRS 639.210(4).

COUNT FIVE

Violation of State Law –Managing Pharmacist Serving on Part-Time Basis

25. By employing Nguyen as a managing pharmacist on a part-time basis, who was not on duty in the pharmacy and active in the management of the pharmacy full-time, Respondents, and each of them, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.220(3)(b), and are subject to discipline pursuant to NRS 639.210(12).

COUNT SIX

Violation of State Law –Acquisition of Pharmacy Stock by Unauthorized Personnel

26. By permitting Macintosh as a pharmaceutical technician to place orders for pharmacy stock in Nguyen's absence, Respondents, and each of them, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.1371(5), NAC 639.245, NAC 639.510(2), NAC 639.700 and/or NAC 639.702, and are subject to discipline pursuant to NRS 639.210(12).

COUNT SEVEN

Managing Pharmacist Responsibility

(Respondent Nguyen)

27. As the managing pharmacist of Las Vegas Community Pharmacy at the time of the violations of law as alleged herein, Nguyen is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

COUNT EIGHT

Pharmacy/Pharmacy Owner Responsibility

(Respondents Las Vegas Community Pharmacy and Macintosh)

28. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondents Las Vegas Community Pharmacy and Macintosh are responsible for those violations and subject to discipline pursuant to NRS 639.210, NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to pharmacy license and registrations of these respondents.

Signed this 26th day of September 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NATALIE NHU NGUYEN, RPH,** **Certificate of Registration No. 18735,** **Respondent.**	**CASE NO. 24-133-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a First Amended Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 2nd day of September 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **NATALIE NHU NGUYEN, RPH,** **Certificate of Registration No. 18735,** **Respondent.**	**Case No. 24-133-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the First Amended Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the First Amended Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the First Amended Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Natalie Nhu Nguyen, RPh

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 30th day of September 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Las Vegas Community Pharmacy
3200 N Soaring Gulls Dr., Suite 101
Las Vegas, NV 89129

Natalie Nguyen, RPh
[redacted]
Las Vegas, NV [redacted]

QHR Pharmacy
c/o Natalie Nguyen, RPh
3375 E Russell Rd 1G
Las Vegas, NV 89120

Ali Macintosh, PT
[redacted]
Las Vegas, NV [redacted]

Evergreen Pharmacy
c/o Ali Macintosh, PT
[redacted]
Las Vegas, NV [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
NOV 2 6 2025
NEVADA STATE BOARD
OF PHARMACY

Aniela K. Szymanski, Esq.
Nevada Bar No. 15822
3765 E. Sunset Rd. B9
Las Vegas NV 89120
702-899-8180
aniela@anielalaw.com
Attorney for Respondent, Natalie Nhu Nguyen, RPH

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, vs. LAS VEGAS COMMUNITY PHARMACY, ET AL., Respondents.	Case No.: 24-133-PH-S 24-133-RPH-S 24-133-PT-S

RESPONDENT NATALIE NHU NGUYEN'S ANSWER AND NOTICE OF DEFENSE

COMES NOW NATALIE NHU NGUYEN, RPH, by and through counsel Aniela K. Szymanski, Esq., and hereby answers the First Amended Notice of Intended Action and Accusation on file as follows:

1. As to paragraphs 3, 21-28 the Respondent denies the allegations contained therein.
2. As to paragraphs 1, 2 the Respondent admits.
3. As to paragraphs 4-7, Respondent is without sufficient knowledge to admit or deny the allegations contained therein, and therefore denies the same.
4. Paragraphs 8-20 are purported statements of law and require no response.

Respondent Nguyen, places on notice the Petitioner that she intends to defend against said accusations.

///

///

WHEREFORE, Respondent prays for the following relief:

1. That the Board hear Respondent's evidence and argument at a hearing;
2. That she be permitted to maintain her license in good standing;.
3. Any further relief as deemed appropriate by law or regulation.

DATED this 26th day of November 2025.

/s/ Aniela K Szymanski
ANIELA K SZYMANSKI
Attorney for Respondent
Natalie Nhu Nguyen

CERTIFICATE OF SERVICE

I hereby certify that on November 26, 2025, I caused this Answer and Notice of Defense to be e-served on all relevant parties to this case via email including:

TeamBC@pharmacy.nv.gov

bkandt@pharmacy.nv.gov.

Dated this 26th day of November 2025.

/s/ Aniela K Szymanski
ANIELA K SZYMANSKI

5G

FILED
SEP 28 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LAS VEGAS COMMUNITY PHARMACY, Pharmacy License No. PH04396,** **NATALIE NHU NGUYEN, RPH, Certificate of Registration No. 18735, and** **ALI MACINTOSH, PT Certificate of Registration No. PT26920,** **Respondents.**	**CASE NOS. 24-133-PH-S** **24-133-RPH-S** **24-133-PT-S** **FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because at the time of the events alleged herein, Respondent Las Vegas Community Pharmacy, License No. PH04396, was a pharmacy licensed by the Board, Natalie Nhu Nguyen, RPh (Nguyen), Certificate of Registration No. 18735, was a pharmacist registered with the Board, and Ali Macintosh, PT (Macintosh), Certificate of Registration No. PT26920, was a pharmaceutical technician registered with the Board.

FACTUAL ALLEGATIONS

2. Macintosh owned Las Vegas Community Pharmacy at the time of the events alleged herein.

3. Nguyen was employed as managing pharmacist by Las Vegas Community Pharmacy from August 31, 2023, until approximately October 14, 2024; however, Nguyen was

employed on a part-time basis and not on duty in the pharmacy and active in the management of the pharmacy full-time.

4. On or about April 10, 2024, an annual inspection of Las Vegas Community Pharmacy revealed evidence in the form of supplier invoices and shipping confirmations that the pharmacy purchased drug products through MatchRX.

5. MatchRX, located in Michigan, is not licensed to engage in business as a wholesaler in Nevada.

6. Macintosh placed the orders with MatchRX in Nguyen's absence.

7. On or about October 10, 2024, the Board issued and served upon MatchRX an Order to Cease-and-Desist together with Citation and Fine for unlicensed wholesale distribution into Nevada.

APPLICABLE LAW

8. The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54), enacted by Congress on November 27, 2013, added Section 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 582 of the FD&C Act (21 U.S.C. § 360eee-1) establishes the requirements that certain entities in the pharmaceutical distribution supply chain, including pharmacies, must follow related to product tracing, verification, and authorized trading partners. Failure to comply is a prohibited act under 21 U.S.C. § 331(t).

9. Any person who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license pursuant to the provisions of NRS Chapter 639. NRS 639.100; NRS 639.233(1). Engaging in the business of wholesale distribution without a license is a felony. NRS 639.100(2).

10. Every wholesale distributor who engages in wholesale distributions of prescription drugs in interstate commerce must be licensed by the state into which the drug is distributed. 21 U.S.C. § 353(e)(1)(A); 21 CFR § 205.4.

11. Purchasing a drug from an unlicensed wholesaler does not constitute a bona fide transaction. NRS 639.595.

12. Performing any duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

13. Aiding or abetting a person not licensed in the State of Nevada constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

14. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(11).

15. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any issued by the Board. NRS 639.210(12).

16. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.210(12) and (15); NRS 639.220(1); NAC 639.702.

17. A managing pharmacist shall be on duty in the pharmacy and active in the management of the pharmacy full-time. NRS 639.220(3)(b).

18. A managing pharmacist of a pharmacy shall be responsible for, and must have knowledge and control of, the acquisition and disposition by the pharmacy of the stock of the pharmacy and shall ensure that the records relating to the acquisition or disposition of the stock of the pharmacy are maintained as required by law. NAC 639.510(2).

19. A pharmaceutical technician may only performs those functions permitted by law. NRS 639.1371(5); NAC 639.245; NAC 639.700; NAC 639.702.

20. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violation of Federal Law - Aiding and Abetting Unlicensed Wholesale Distribution

21. By purchasing drug products through MatchRX, a company not licensed to engage in the business of wholesale distribution into Nevada, Respondents, and each of them, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 360eee-1, 21 U.S.C. § 331(t), 21 U.S.C. § 353(e)(1)(A) and/or 21 CFR Part 205, and are subject to discipline pursuant to NRS 639.210(11).

COUNT TWO

Violation of State Law - Aiding and Abetting Unlicensed Wholesale Distribution

22. By purchasing drug products through MatchRX, a company not licensed to engage in the business of wholesale distribution into Nevada, Respondents, and each of them, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.100, NRS 639.233(1) and/or NRS 639.595, and are subject to discipline pursuant to NRS 639.210(12).

COUNT THREE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

23. By their actions as alleged herein, Respondents, and each of them, performed their respective duties in an incompetent, unskillful or negligent manner, engaged in unprofessional conduct as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 639.210(4).

COUNT FOUR

Unprofessional Conduct – Aiding and Abetting Unlicensed Wholesale Distribution

24. By purchasing drug products through MatchRX, a company not licensed to engage in the business of wholesale distribution into Nevada, Respondents, and each of them, aided and abetted unlicensed wholesale distribution, engaged in unprofessional conduct as defined in NAC 639.945(1)((j), and are subject to discipline pursuant to NRS 639.210(4).

COUNT FIVE

Violation of State Law –Managing Pharmacist Serving on Part-Time Basis

25. By employing Nguyen as a managing pharmacist on a part-time basis, who was not on duty in the pharmacy and active in the management of the pharmacy full-time, Respondents, and each of them, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.220(3)(b), and are subject to discipline pursuant to NRS 639.210(12).

COUNT SIX

Violation of State Law –Acquisition of Pharmacy Stock by Unauthorized Personnel

26. By permitting Macintosh as a pharmaceutical technician to place orders for pharmacy stock in Nguyen's absence, Respondents, and each of them, violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.1371(5), NAC 639.245, NAC 639.510(2), NAC 639.700 and/or NAC 639.702, and are subject to discipline pursuant to NRS 639.210(12).

COUNT SEVEN

Managing Pharmacist Responsibility
(Respondent Nguyen)

27. As the managing pharmacist of Las Vegas Community Pharmacy at the time of the violations of law as alleged herein, Nguyen is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

COUNT EIGHT

Pharmacy/Pharmacy Owner Responsibility

(Respondents Las Vegas Community Pharmacy and Macintosh)

28. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondents Las Vegas Community Pharmacy and Macintosh are responsible for those violations and subject to discipline pursuant to NRS 639.210, NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to pharmacy license and registrations of these respondents.

Signed this 2nd day of SEPTEMBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ALI MACINTOSH, PT** **Certificate of Registration No. PT26920,** **Respondent.**	**CASE NO. 24-133-PT-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a First Amended Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, January 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 28th day of SEPTEMBER 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ALI MACINTOSH, PT** **Certificate of Registration No. PT26920,** **Respondent.**	**Case No. 24-133-PT-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the First Amended Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the First Amended Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the First Amended Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Ali Macintosh, PT

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 30th day of September 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Las Vegas Community Pharmacy
3200 N Soaring Gulls Dr., Suite 101
Las Vegas, NV 89129

Natalie Nguyen, RPh
[redacted]
Las Vegas, NV [redacted]

QHR Pharmacy
c/o Natalie Nguyen, RPh
3375 E Russell Rd 1G
Las Vegas, NV 89120

Ali Macintosh, PT
[redacted]
Las Vegas, NV [redacted]

Evergreen Pharmacy
c/o Ali Macintosh, PT
[redacted]
Las Vegas, NV [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

5H

FILED
JUN 15 2026
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **HISBAY HAIDER ALI, MD,** **Certificate of Registration No., CS31898,** **Respondent.**	**Case No. 24-444-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this Respondent because at the time of the events alleged herein, Respondent Hisbay Haider Ali, MD, held a Nevada controlled substance registration, Certificate of Registration No. CS31898, issued by the Board.

FACTUAL ALLEGATIONS

2. From October 11, 2022, to October 11, 2024, Respondent issued four thousand six hundred and twenty (4,620) controlled substance prescriptions for five hundred and sixty-five (565) unique patients, but only reviewed a patient's utilization report in the Prescription Monitoring Program (PMP) database on ten (10) occasions.

3. Respondent has failed to query and review for accuracy his MyRx prescriber activity report in the PMP database at least once every 6 months as required by law.

4. On or about October 11, 2024, the Nevada State Board of Medical Examiners (NSBME) filed charges and summarily suspended Respondent's License No. 20660 to practice

medicine for engaging in conduct in violation of NRS Chapter 630 in Case Nos. 24-53581-1, 24-53581-2 and 24-53581-3.

5. On or about November 4, 2024, Board staff served Respondent with notice that the suspension of his NSBME License No. 20660 to practice medicine operated as an immediate suspension of his Certificate of Registration No. CS31898 with the Board pursuant to NRS 639.2107, and that Respondent must immediately cease and desist possessing, administering and/or prescribing controlled substances for Nevada patients.

6. On or about November 7, 2024, Respondent surrendered his Registration No. FA6780779 to the Drug Enforcement Administration by executing a DEA Form 104 – "Surrender for Cause of DEA Certificate of Registration."

7. Respondent failed to fully disclose to the Board the pending charges in NSBME Case Nos. 24-53581-1, 24-53581-2 and 24-53581-3 on his 2024 biennial renewal application for Certificate of Registration No. CS31898.

8. On June 6, 2025, the NSBME and Respondent entered into a settlement agreement in Case Nos. 24-53581-1, 24-53581-2 and 24-53581-3 imposing discipline upon Respondent; Respondent admitted to most of the charges and Respondent's License No. 20660 to practice medicine remained suspended for six (6) months.

9. On March 3, 2026, the NSBME filed charges and summarily suspended Respondent's License No. 20660 to practice medicine in Case No. 26-53581-1 for violating the settlement agreement in Case Nos. 24-53581-1, 24-53581-2 and 24-53581-3.

10. On March 4, 2026, Respondent appeared before Board on an application to have his controlled substance registration reinstated and while under oath failed to disclose the current suspension of his NSBME License No. 20660 to practice medicine; the Board approved his application.

APPLICABLE LAW

11. A practitioner must hold a license to practice his or her profession in this State and be registered with both the DEA and the Board to possess, administer, prescribe and/or otherwise dispense any controlled substance in Nevada. 21 U.S.C. § 822(a)(2) and (e)(1); 21 U.S.C. § 823(f); 21 C.F.R. § 1301.12; 21 CFR § 1306.03(a)(1); NRS 453.226(1); NRS 453.321(1)(a); NRS 639.100(1); NRS 639.235(1).

12. A practitioner shall only issue a controlled substance prescription after review of a patient's utilization report in the PMP database in conformance with NRS 639.23507.

13. A practitioner shall review his or her MyRx prescriber activity report in the PMP database for accuracy at least once every 6 months. NRS 453.164(7).

14. It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 639. NRS 639.281(1).

15. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

16. Willfully making to the Board any false statement which is material to the administration or enforcement of Nevada law is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9).

17. Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

18. The Board may suspend or revoke a registration if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

19. The Board may suspend or revoke a registration if the holder has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

20. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violation of State Law – Failure to Review Patient Utilization Report

21. By failing to review patient utilization reports in the PMP database prior to issuing controlled substance prescriptions as alleged in paragraph 2 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.23507, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT TWO

Violations of State Law – Failure to Review MyRx Prescriber Activity Report

22. By failing to query to query and review for accuracy his MyRx prescriber activity report in the PMP database as alleged in paragraph 3 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.164(7), and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT THREE

Furnishing False Material Information to Board

23. By failing to fully disclose to the Board the pending charges in NSBME Case Nos. 24-53581-1, 24-53581-2 and 24-53581-3 on his 2024 biennial renewal application for Certificate of Registration No. CS31898 as alleged in paragraph 7 herein, and by failing to

disclose the current suspension of his NSBME License No. 20660 to practice medicine when appearing before the Board on March 4, 2026, as alleged in paragraph 10 herein, Respondent violated NRS 639.281(1) and is subject to discipline pursuant to NRS 639.210(9) and/or NRS 639.210(12).

COUNT FOUR

Obtaining Registration by False or Fraudulent Application

24. By failing to fully disclose to the Board the pending charges in NSBME Case Nos. 24-53581-1, 24-53581-2 and 24-53581-3 on his 2024 biennial renewal application for Certificate of Registration No. CS31898 as alleged in paragraph 7 herein, and by failing to disclose the current suspension of his NSBME License No. 20660 to practice medicine when current suspension of his NSBME License No. 20660 to practice medicine when appearing before the Board on March 4, 2026, as alleged in paragraph 10 herein, Respondent is subject to discipline pursuant to NRS 639.210(10).

COUNT FIVE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

25. By his actions and omissions as alleged herein, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1), NRS 639.210(4) and/or NRS 639.23916(3)(b).

COUNT SIX

Commission of Acts that Render Registration Inconsistent with the Public Interest

26. By his actions and omissions as alleged herein, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1)(e) and NRS 453.241(1).

\\\

\\\

COUNT SEVEN
Not Qualified for Registration

27. By the suspension of his NSBME License No. 20660 to practice medicine and the surrender of his DEA Registration No. FA6780779 for cause, Respondent no longer qualifies for registration to dispense controlled substances under federal or state law and his Certificate of Registration No. CS31898 is subject to revocation pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 15th day of JUNE 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **HISBAY HAIDER ALI, MD,** **Certificate of Registration No., CS31898,** **Respondent.**	**Case No. 24-444-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, July 15, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 15th day of JUNE 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **HISBAY HAIDER ALI, MD,** **Certificate of Registration No., CS31898,** **Respondent.**	**Case No. 24-444-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

HISBAY HAIDER ALI, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 16th day of June 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Hisbay Ali, MD
c/o Hope LLC
500 N Rainbow Blvd., Ste. 313
Las Vegas, NV 89107

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 25th day of June 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Hisbay Ali, MD
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

51

FILED
MAR 3 0 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **US PHARMACY,** **Pharmacy License No. PH04415, and** **FERNESSER TRACEY, RPH,** **Certificate of Registration No. 09913,** **Respondents.**	**CASE NOS. 25-175-PH-S** **25-175-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Fernesser Tracey, RPh (Tracey), Certificate of Registration No. 09913, was a pharmacist registered with the Board, and Respondent US Pharmacy, Pharmacy License No. PH04415, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Respondent Tracey was managing pharmacist of Respondent US Pharmacy, located in Las Vegas, during the relevant times frame herein.

3. In May 2025, Board staff investigating Respondent US Pharmacy's operations determined that US Pharmacy's computer system does not capture, nor has the option to record, the initials of the pharmaceutical technician performing functions pursuant to NAC 639.245(2)(b), specifically, counting medication that will be dispensed to a patient. Additionally, if a modification is made to a prescription, US Pharmacy's computer system does not capture the type of modification made.

APPLICABLE LAW

4. A prescription prepared by a pharmaceutical technician must bear the legible initials of the pharmaceutical technician, either handwritten or recorded in the pharmacy's computer system. NAC 639.252(1); NAC 639.751.

5. Any computerized system used by a pharmacy for recording information concerning prescriptions must be designed in such a manner that it provides a readily retrievable printed record of the information relating to a prescription or a patient which the pharmacy is required to maintain pursuant to state or federal law, including, without limitation, information relating to the original prescription or the refill or modification of that prescription. NAC 639.910(1)(a).

6. A pharmacy's computer system must conform to the requirements of NAC 639.930 with safeguards against access to and modification or manipulation of information.

7. A pharmacy's computer system must conform to the requirements of NAC 639.935, and be able to produce a printed record of history of each prescription filled by the pharmacy, including the modification or manipulation of information concerning the prescription.

8. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

9. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy, including recordkeeping. NRS 639.210(12) and (15); NRS 639.220(1).

10. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5). Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE
Violations of State Law – Recordkeeping
(Respondent US Pharmacy)

11. Respondent US Pharmacy, Respondent Tracey and/or pharmacy personnel violated NAC 639.252, 639.751, 639.910, 639.930 and/or 639.935 as alleged in paragraph 3 herein, and are subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1), NRS 639.230(5) and/or NAC 639.945(3).

COUNT TWO
Managing Pharmacist Responsibility
(Respondent Tracey)

11. As the managing pharmacist of Respondent US Pharmacy at the time of the errors, omissions and violations alleged herein, Respondent Tracey is responsible and subject to discipline pursuant to NRS 639.210(15) and/or NRS 639.220(1).

COUNT THREE
Pharmacy/Pharmacy Owner Responsibility
(Respondent US Pharmacy)

12. As the pharmacy/pharmacy owner at the time of the errors, omissions and violations alleged herein, Respondent US Pharmacy is responsible pursuant to NRS 639.230(5) and/or NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration and pharmacy license of these Respondents.

Signed this 30th day of MARCH 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **US PHARMACY,** **Pharmacy License No. PH04415, and** **FERNESSER TRACEY, RPH,** **Certificate of Registration No. 09913,** **Respondents.**	**Case Nos. 25-175-PH-S** **25-175-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, June 3, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. . At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 30th day of MARCH 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **US PHARMACY,** **Pharmacy License No. PH04415,** **Respondent.**	**Case No. 25-175-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

AUTHORIZED REPRESENTATIVE FOR US PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 31st day of March 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

US Pharmacy
3871 S. Valley View Blvd., Suite 13
Las Vegas, NV 89103

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
MAY 10 2026
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. US PHARMACY, Pharmacy License No. PH04415, and, FERNESSER TRACEY, RPH, Certificate of Registration No. 09913, Respondents.	Case Nos. 25-175-PH-S 25-175-RPH-S

ANSWER TO COMPLAINT

Respondent, US PHARMACY, ("Respondent") by and through its counsel of record, HUTCHISON & STEFFEN, PLLC, answers the Complaint as follows:

JURISDICTION

1. Answering Paragraph 1 of the Complaint, Respondent admits it was a pharmacy licensed by the Board. As to the remaining allegations, Respondent states that it is without knowledge and or information sufficient to form a belief as to the truth of the remaining allegations contained in said paragraph and therefore denies the allegations contained therein.

FACTUAL ALLEGATIONS

2. Answering Paragraph 2 of the Complaint, Respondent admits the allegations contained in said paragraph.

3. Answering Paragraph 3 of the Complaint, Respondent states that it is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

///

///

APPLICABLE LAW

4. Answering Paragraph 4 of the Complaint, Respondent states the paragraph is a restatement of statute and does not contain any factual allegations that can be admitted or denied. To the extent that the allegations differ or extrapolate upon the statute, Respondent states that she is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

5. Answering Paragraph 5 of the Complaint, Respondent states the paragraph is a restatement of statute and does not contain any factual allegations that can be admitted or denied. To the extent that the allegations differ or extrapolate upon the statute, Respondent states that she is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

6. Answering Paragraph 6 of the Complaint, Respondent states the paragraph is a restatement of statute and does not contain any factual allegations that can be admitted or denied. To the extent that the allegations differ or extrapolate upon the statute, Respondent states that she is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

7. Answering Paragraph 7 of the Complaint, Respondent states the paragraph is a restatement of statute and does not contain any factual allegations that can be admitted or denied. To the extent that the allegations differ or extrapolate upon the statute, Respondent states that she is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

8. Answering Paragraph 8 of the Complaint, Respondent states the paragraph is a restatement of statute and does not contain any factual allegations that can be admitted or denied. To the extent that the allegations differ or extrapolate upon the statute, Respondent states that she is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

///

9. Answering Paragraph 9 of the Complaint, Respondent states the paragraph is a restatement of statute and does not contain any factual allegations that can be admitted or denied. To the extent that the allegations differ or extrapolate upon the statute, Respondent states that she is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein

10. Answering Paragraph 10 of the Complaint, Respondent states the paragraph is a restatement of statute and does not contain any factual allegations that can be admitted or denied. To the extent that the allegations differ or extrapolate upon the statute, Respondent states that she is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

COUNT ONE

Violations of State Law - Recordkeeping
(Respondent US Pharmacy)

11. Answering Paragraph 11 of the Complaint, Respondent denies the allegations contained in said paragraph.

COUNT TWO

Managing Pharmacist Responsibility
(Respondent Tracey)

12. Answering Paragraph 12 of the Complaint, Respondent denies the allegations contained in said paragraph.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The Complaint fails to state claims against Respondent upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The Complaint does not give Respondent the necessary and appropriate notice of claims against it, which is a violation of Respondent's due process rights.

THIRD AFFIRMATIVE DEFENSE

Respondent denies each and every allegation of the Board's Complaint not specifically

admitted or otherwise pled to herein.

FOURTH AFFIRMATIVE DEFENSE

All possible Affirmative Defenses may not have been alleged herein insofar as sufficient facts were not available after reasonable inquiry upon the filing of Respondent's Answer, and therefore, Respondent reserves the right to amend its Answer to allege additional Affirmative Defenses if subsequent investigation warrants.

FIFTH AFFIRMATIVE DEFENSE

Respondent hereby incorporates by reference those affirmative defenses enumerated in NRCP 8 and 12, as if fully set forth herein. In the event further investigation or discovery reveals the applicability of any such defenses, Respondent reserves the right to seek leave of Court to amend her Answer to specifically assert any such defense(s). Such defenses are herein incorporated by reference for the specific purpose of not waiving any such defense.

SIXTH AFFIRMATIVE DEFENSE

It has been necessary for Respondent to employ the services of an attorney to defend this action and a reasonable sum should be allowed to Respondent for attorneys' fees, together with costs of suit incurred herein.

PRAYER FOR RELIEF

WHEREFORE, Respondent prays for judgment as follows:

1. That the Board takes nothing by virtue of its Complaint, and that all allegations against Respondent are dismissed with prejudice;

2. For reasonable attorneys' fees and costs of suit incurred herein;

3. For costs and disbursements incurred herein; and

///

///

///

///

///

4. For such other and further relief as is just and proper.

DATED this 1st day of May 2026.

HUTCHISON & STEFFEN, PLLC

/s/ Jessica R. Gandy

Candace C. Herling, Esq. (NBN. 13503)
Jessica R. Gandy, Esq. (NBN 14202)
Peccole Professional Park
10080 West Alta Drive, Suite 200
Las Vegas, NV 89145
Telephone: (702) 385-2500
Attorneys for Respondents

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **US PHARMACY,** **Pharmacy License No. PH04415, and** **FERNESSER TRACEY, RPH,** **Certificate of Registration No. 09913,** **Respondents.**	**CASE NOS. 25-175-PH-S** **25-175-RPH-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Fernesser Tracey, RPh (Tracey), Certificate of Registration No. 09913, and Respondent US Pharmacy, Pharmacy License No. PH04415, by and through counsel, Jessica R. Gandy, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. On or about March 31, 2026, Respondents were served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. On or about May 1, 2026, Respondents filed an Answer and Notice of Defense to the Accusation.

3. Respondents are fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondents are aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondents have failed to comply with the provisions of this Stipulation, Respondents hereby knowingly and voluntarily waive the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondents do not contest the allegations in the Accusation, but acknowledge that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. In May 2025, Board staff investigating Respondent US Pharmacy's operations determined that US Pharmacy's computer system did not comply with the recordkeeping requirements of NAC 639.252, 639.751, 639.910, 639.930 and/or 639.935;

B. As the managing pharmacist of Respondent US Pharmacy at the time of the errors, omissions and violations alleged herein, Respondent Tracey is responsible and subject to discipline pursuant to NRS 639.210(15) and/or NRS 639.220(1); and

C. As the pharmacy/pharmacy owner at the time of the errors, omissions and violations alleged herein, Respondent US Pharmacy is responsible pursuant to NRS 639.230(5) and/or NAC 639.945(3).

7. Board staff has verified that Respondent US Pharmacy's computer system now fully complies with the recordkeeping requirements of Nevada law.

8. Those violations are plead with particularity in the Amended Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

9. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Fernesser Tracey, RPh, Certificate of Registration No. 09913, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent Tracey shall pay a fine of Two Thousand Dollars ($2,000.00) for the violations; and

B. Pursuant to NRS 622.400, Respondent Tracey shall pay One Thousand Dollars ($1000.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs.

10. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent US Pharmacy, Pharmacy License No. PH04415, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent US Pharmacy shall pay a fine of Four Thousand Dollars ($4,000.00) for the violations; and

B. Pursuant to NRS 622.400, Respondent US Pharmacy shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs.

11. Any failure by either Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing the non-compliant Respondent(s) to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by any Respondent, the Board may impose additional discipline upon the non-compliant Respondent(s) consistent with the provisions of NRS Chapter 639.

12. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 14, 2026. Respondents will appear in person at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondents or counsel are not present at the meeting.

13. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330

and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

14. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

15. Upon approval of this Stipulation by the Board, Respondents shall pay the fines agreed to herein by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2026.

16. Upon approval of this Stipulation by the Board, Respondents shall pay the attorney's fees and investigative costs agreed to herein by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2026.

17. Subject to the approval of this Stipulation by the Board, the Board and Respondents agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondents have fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 9 day of 11 2026

Tania Prieto Hernández

US PHARMACY
Pharmacy License No. PH04415

Signed this 9 day of 11 2026

Fernesser Tracey

FERNESSER TRACEY, RPH
Certificate of Registration No. 09913

APPROVED AS TO FORM AND CONTENT
this ___ day of _____ 2026

JESSICA R. GANDY, ESQ.
Counsel for Respondents

Signed this ___ day of _____ 2026

BRETT KANDT
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Fernesser Tracey, RPh, Certificate of Registration No. 09913, and Respondent US Pharmacy, Pharmacy License No. PH04415, in Case Nos. 25-175-PH-S and 25-175-RPH-S, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of October 2026.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

5J

FILED
MAR 3 0 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **US PHARMACY,** **Pharmacy License No. PH04415, and** **FERNESSER TRACEY, RPH,** **Certificate of Registration No. 09913,** **Respondents.**	**CASE NOS. 25-175-PH-S** **25-175-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Fernesser Tracey, RPh (Tracey), Certificate of Registration No. 09913, was a pharmacist registered with the Board, and Respondent US Pharmacy, Pharmacy License No. PH04415, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Respondent Tracey was managing pharmacist of Respondent US Pharmacy, located in Las Vegas, during the relevant times frame herein.

3. In May 2025, Board staff investigating Respondent US Pharmacy's operations determined that US Pharmacy's computer system does not capture, nor has the option to record, the initials of the pharmaceutical technician performing functions pursuant to NAC 639.245(2)(b), specifically, counting medication that will be dispensed to a patient. Additionally, if a modification is made to a prescription, US Pharmacy's computer system does not capture the type of modification made.

APPLICABLE LAW

4. A prescription prepared by a pharmaceutical technician must bear the legible initials of the pharmaceutical technician, either handwritten or recorded in the pharmacy's computer system. NAC 639.252(1); NAC 639.751.

5. Any computerized system used by a pharmacy for recording information concerning prescriptions must be designed in such a manner that it provides a readily retrievable printed record of the information relating to a prescription or a patient which the pharmacy is required to maintain pursuant to state or federal law, including, without limitation, information relating to the original prescription or the refill or modification of that prescription. NAC 639.910(1)(a).

6. A pharmacy's computer system must conform to the requirements of NAC 639.930 with safeguards against access to and modification or manipulation of information.

7. A pharmacy's computer system must conform to the requirements of NAC 639.935, and be able to produce a printed record of history of each prescription filled by the pharmacy, including the modification or manipulation of information concerning the prescription.

8. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

9. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy, including recordkeeping. NRS 639.210(12) and (15); NRS 639.220(1).

10. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5). Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE
Violations of State Law – Recordkeeping
(Respondent US Pharmacy)

11. Respondent US Pharmacy, Respondent Tracey and/or pharmacy personnel violated NAC 639.252, 639.751, 639.910, 639.930 and/or 639.935 as alleged in paragraph 3 herein, and are subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1), NRS 639.230(5) and/or NAC 639.945(3).

COUNT TWO
Managing Pharmacist Responsibility
(Respondent Tracey)

11. As the managing pharmacist of Respondent US Pharmacy at the time of the errors, omissions and violations alleged herein, Respondent Tracey is responsible and subject to discipline pursuant to NRS 639.210(15) and/or NRS 639.220(1).

COUNT THREE
Pharmacy/Pharmacy Owner Responsibility
(Respondent US Pharmacy)

12. As the pharmacy/pharmacy owner at the time of the errors, omissions and violations alleged herein, Respondent US Pharmacy is responsible pursuant to NRS 639.230(5) and/or NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration and pharmacy license of these Respondents.

Signed this 30 day of MARCH 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **US PHARMACY,** **Pharmacy License No. PH04415, and** **FERNESSER TRACEY, RPH,** **Certificate of Registration No. 09913,** **Respondents.**	**Case Nos. 25-175-PH-S** **25-175-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, June 3, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 30th day of MARCH 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FERNESSER TRACEY, RPH,** **Certificate of Registration No. 09913,** **Respondent.**	**Case No. 25-175-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

FERNESSER TRACEY, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 31st day of March 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Fernesser Tracey, RPH
[redacted]
Las Vegas, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **US PHARMACY,** **Pharmacy License No. PH04415, and** **FERNESSER TRACEY, RPH,** **Certificate of Registration No. 09913,** **Respondents.**	**CASE NOS. 25-175-PH-S** **25-175-RPH-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Fernesser Tracey, RPh (Tracey), Certificate of Registration No. 09913, and Respondent US Pharmacy, Pharmacy License No. PH04415, by and through counsel, Jessica R. Gandy, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. On or about March 31, 2026, Respondents were served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. On or about May 1, 2026, Respondents filed an Answer and Notice of Defense to the Accusation.

3. Respondents are fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondents are aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondents have failed to comply with the provisions of this Stipulation, Respondents hereby knowingly and voluntarily waive the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondents do not contest the allegations in the Accusation, but acknowledge that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. In May 2025, Board staff investigating Respondent US Pharmacy's operations determined that US Pharmacy's computer system did not comply with the recordkeeping requirements of NAC 639.252, 639.751, 639.910, 639.930 and/or 639.935;

B. As the managing pharmacist of Respondent US Pharmacy at the time of the errors, omissions and violations alleged herein, Respondent Tracey is responsible and subject to discipline pursuant to NRS 639.210(15) and/or NRS 639.220(1); and

C. As the pharmacy/pharmacy owner at the time of the errors, omissions and violations alleged herein, Respondent US Pharmacy is responsible pursuant to NRS 639.230(5) and/or NAC 639.945(3).

7. Board staff has verified that Respondent US Pharmacy's computer system now fully complies with the recordkeeping requirements of Nevada law.

8. Those violations are plead with particularity in the Amended Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

9. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Fernesser Tracey, RPh, Certificate of Registration No. 09913, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent Tracey shall pay a fine of Two Thousand Dollars ($2,000.00) for the violations; and

B. Pursuant to NRS 622.400, Respondent Tracey shall pay One Thousand Dollars ($1000.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs.

10. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent US Pharmacy, Pharmacy License No. PH04415, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent US Pharmacy shall pay a fine of Four Thousand Dollars ($4,000.00) for the violations; and

B. Pursuant to NRS 622.400, Respondent US Pharmacy shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs.

11. Any failure by either Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing the non-compliant Respondent(s) to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by any Respondent, the Board may impose additional discipline upon the non-compliant Respondent(s) consistent with the provisions of NRS Chapter 639.

12. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 14, 2026. Respondents will appear in person at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondents or counsel are not present at the meeting.

13. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330

and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

14. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

15. Upon approval of this Stipulation by the Board, Respondents shall pay the fines agreed to herein by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2026.

16. Upon approval of this Stipulation by the Board, Respondents shall pay the attorney's fees and investigative costs agreed to herein by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2026.

17. Subject to the approval of this Stipulation by the Board, the Board and Respondents agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondents have fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 9 day of 11 2026

Tania Prieto Hernández

US PHARMACY
Pharmacy License No. PH04415

Signed this 9 day of 11 2026

Fernesser Tracey

FERNESSER TRACEY, RPH
Certificate of Registration No. 09913

APPROVED AS TO FORM AND CONTENT
this ___ day of _____ 2026

JESSICA R. GANDY, ESQ.
Counsel for Respondents

Signed this ___ day of _____ 2026

BRETT KANDT
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Fernesser Tracey, RPh, Certificate of Registration No. 09913, and Respondent US Pharmacy, Pharmacy License No. PH04415, in Case Nos. 25-175-PH-S and 25-175-RPH-S, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of October 2026.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

5K

FILED
JUL 2 1 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMERICAN WELLNESS PHARMACY, Pharmacy License No. PH02705, and** **JAMES MICHAEL BARBER, RPH, Certificate of Registration No. 24357,** **Respondents.**	**CASE NOS. 25-464-PH-S** **25-464-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent James Michael Barber, RPh (Barber), Certificate of Registration No. 24357, was a pharmacist registered with the Board, and Respondent American Wellness Pharmacy, Pharmacy License No. PH02705, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Respondent American Wellness Pharmacy has a record of prior discipline from the Board in case no. 23-063-PH-S, a stipulated settlement entered September 4, 2024, and amended October 16, 2024, and January 15, 2025, arising from Respondent's compounding and dispensing drug products in violation of NAC 639.661-.690, *inclusive*, and related federal law, 21 U.S.C. § 353a.

3. Barber was employed as managing pharmacist by American Wellness Pharmacy at the time of the events alleged herein.

4. Board staff determined during an inspection/audit in November 2025 that Respondents compounded and dispensed sterile injectable drug products to patients in Nevada that were essentially copies of tirzepatide while the drug product was commercially available, and without a "statement of significant difference" for each prescription documenting a medical need specific to the patient for the compounded product, including, without limitation, the following prescriptions for tirzepatide w/ B6 12-0.1 mg/ml 1ml vial injection:

Prescription No. 6091671: patient J.P.; issued 9/22/25 and dispensed 9/25/25

Prescription No. 6091666: patient M.K.; issued 9/22/25 and dispensed 9/25/25

Prescription No. 6091767: patient M.G.; issued 9/24/25 and dispensed 9/25/25

Prescription No. 6092002: patient J.T.; issued 9/30/25 and dispensed 9/30/25

Prescription No. 6092081: patient E.B.; issued 10/1/25 and dispensed 10/1/25

5. During that inspection/audit Board staff also determined that Respondents accepted and filled dangerous drug prescriptions with a stamped signature from the practitioner.

6. Board staff subsequently determined during an investigation in February-March 2026 that Respondents compounded and dispensed additional drug products to patients in Nevada that were essentially copies of commercially available drug products without a "statement of significant difference" for each prescription, including, without limitation, the following prescriptions:

Prescription No. 6093041: patient A.T. from practitioner A.F.; verbally transcribed 10/22/25 for "testosterone cypionate 200mg/ml in MCT oil"

Prescription No. 6094596: patient A.Z. from practitioner R.T.; verbally transcribed for 11/25/25 for "testosterone 50mg/ml"

Prescription No. 6095471: patient S.S. issued electronically 12/12/25 for "tirzepatide-l carnitine12-100 mg/ml INJECTION"

Prescription No. 6095935: patient M.F. issued electronically 12/26/25 for "tirzepatide-l carnitine 12-100 mg/ml injectable"

Prescription No. 6096364: patient M.R. issued electronically 1/6/26 for "testosterone cypionate 50mg/ml" with directions to "compound in grape seed oil"

7. During that investigation Board staff also determined that Respondents accepted and filled controlled substance prescriptions given by oral order from the practitioner, including, without limitation, the following prescriptions:

Prescription No. 6093041: patient A.T. from practitioner A.F.; verbally transcribed 10/22/25 for "testosterone cypionate 200mg/ml in MCT oil"

Prescription No. 6094596: patient A.Z. from practitioner R.T.; verbally transcribed for 11/25/25 for "testosterone 50mg/ml"

Prescription No. 6097319: patient MC. From practitioner J.N.; verbally transcribed 1/23/26 for "testosterone cyp 50mg/ml"

8. On April 1, 2026, Board inspectors conducting an inspection determined that Respondents were compounding sterile and non-sterile drug products out of compliance with chapter 800 of the *United States Pharmacopeia - National Formulary* (USP-800) as follows:

A. The location stores HD API products for non-sterile compounding in a room that is neutral pressure to surrounding areas, is not externally ventilated, and has never been tested for air exchanges per hour. Per USP-800 guidelines all HD API's must be stored in a room that is externally ventilated, has negative pressure to surrounding areas, and has at least 12 air exchanges per hour.

B. The location stores HD API products for sterile compounding in a room that is positive pressure to surrounding areas and is not externally ventilated. See comment #1 for USP-800 requirements.

C. The location compounds non-sterile HD API products in a hood located in a separate room from the retail and sterile compounding area. The room would be defined as the C-SEC (containment secondary engineering control). The room used for non-sterile hazardous

compounding is not externally vented, has never been tested for air exchanges per hour, and is neutral pressure compared to surrounding areas. Per USP-800 guidelines the room must be externally vented, have at least 12 air exchanges per hour, and have a negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas.

D. The location compounds sterile HD API products in a hood located in an ISO-7 classified buffer room. The room is not externally vented and is positive pressure in relation to adjacent areas. Per USP-800 guidelines the room must be externally vented and have a negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas.

E. The location compounds sterile HD API products in a biological safety cabinet that has been certified by an outside agency. The BSC is located in an ISO-7 classified buffer room. The BSC is not externally vented. Per USP-800 guidelines the BSC must be externally vented.

F. The location compounds sterile HD API products in an ISO-7 classified buffer room. The adjacent ante room is an ISO-8 classified ante room. Per USP -800 guidelines the ante room for sterile hazardous compounding must be an ISO-7 classified area.

9. On or about April 6, 2026, Board staff served Respondents with an order to cease-and-desist compounding sterile and non-sterile drug products in violation of chapter 800 of the United States Pharmacopeia - National Formulary (USP-800).

APPLICABLE LAW

10. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products in Nevada shall comply with the provisions of NAC 639.661 -.690, *inclusive*, as amended by LCB File No. R053-24, and related federal law, 21 U.S.C. § 353a, the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishing national standards for compounding medications. This includes, without limitation, compliance with chapter 800 of the *United States Pharmacopeia - National Formulary* (USP-800) as applicable.

11. Federal law prohibits compounding a drug product that is essentially a copy of a commercially available product. 21 U.S.C. § 353a(b)(1)(D). Pursuant to section 503A(b)(2) of

the FD&C Act (21 U.S.C. § 353a(b)(2)), a compounded drug product is not essentially a copy of a commercially available drug product if a change is made for an identified individual patient, and the prescribing practitioner has determined that the change will produce a significant difference for that patient. If a compounder intends to rely on such a determination to establish that a compounded drug is not essentially a copy of a commercially available drug product, the compounder should ensure that the determination is documented on the prescription in a "statement of significant difference."

12. A written prescription for a dangerous drug must contain in pertinent part the original handwritten signature of the prescribing practitioner in nonerasable ink. NRS 454.223(2)(a); NRS 639.2353(2)(a); NAC 454.060.

13. A prescription for a controlled substance must be given to a pharmacy by electronic transmission in accordance with the regulations adopted by the Board. NRS 639.23535(1); 21 CFR Part 1311.

14. Performing any duties as the holder of a license or registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

15. The Board may suspend or revoke a license or registration if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

16. The Board may suspend or revoke a license or registration if the holder has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

17. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the

pharmacy and the practice of pharmacy, including recordkeeping. NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

18. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of a pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violations of Federal and State Law – Compounding Drug Products that are Essentially Copies of Commercially Available Drug Products Without a Statement of Significant Difference

19. By compounding drug products to patients in Nevada that were essentially copies of commercially available drug products, as alleged in paragraphs 4 and 6 herein, Respondents and/or Respondents' personnel violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 353a(b)(1)(D) and Section 3 of LCB File No. R053-24, and Respondents are therefore subject to discipline pursuant to NRS 639.210(11), (12) and (15), NRS 639.220(1), NRS 639.230(5), NAC 639.702, and/or NAC 639.945(3).

COUNT TWO

Violations of State Law – Filling Dangerous Drug Prescriptions Without an Original Signature from the Prescribing Practitioner

20. By filling and dispensing dangerous drug prescriptions with a stamped signature from the practitioner, as alleged in paragraph 5 herein, Respondents and/or Respondents' personnel violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.223(2)(a), NRS 639.2353(2)(a) and/or NAC 454.060, and Respondents are therefore subject to discipline pursuant to NRS 639.210(11), (12) and (15), NRS 639.220(1), NRS 639.230(5), NAC 639.702, and/or NAC 639.945(3).

COUNT THREE

Violations of Federal and State Law – Filling Controlled Substance Not Given by Electronic Transmission from the Prescribing Practitioner

21. By filling and dispensing controlled substance prescriptions given by oral order from the practitioner, as alleged in paragraph 5 herein, Respondents and/or Respondents' personnel violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.23535(1) and/or 21 CFR Part 1311, and Respondents are therefore subject to discipline pursuant to NRS 639.210(11), (12) and (15), NRS 639.220(1), NRS 639.230(5), NAC 639.702, and/or NAC 639.945(3).

COUNT FOUR

Violations of Federal and State Law – Compounding Sterile and Non-sterile Drug Products Out of Compliance with USP-800

22. By compounding sterile and non-sterile drug products out of compliance with USP-800, as alleged in paragraph 8 herein, Respondents and/or Respondents' personnel violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NAC 639.661 - .690, *inclusive*, as amended by LCB File No. R053-24, and related federal law, 21 U.S.C. § 353a, and Respondents are therefore subject to discipline pursuant to NRS 639.210(11), (12) and (15), NRS 639.220(1), NRS 639.230(5), NAC 639.702, and/or NAC 639.945(3).

COUNT FIVE

Unprofessional Conduct – Negligence in Compounding and Dispensing Drug Products

23. By their acts as alleged herein, Respondents and/or Respondents' personnel engaged in unprofessional conduct as defined in NAC 639.945(1)((i), and Respondents are therefore subject to discipline pursuant to NRS 639.210(4), NRS 639.220(1), NRS 639.230(5), NAC 639.702, and/or NAC 639.945(3).

COUNT SIX

Managing Pharmacist Responsibility (Respondent Barber)

24. As the managing pharmacist of Respondent American Wellness Pharmacy at the time of the errors, omissions and violations alleged herein, Respondent Barber is responsible and

subject to discipline pursuant to NRS 639.210(4), (11), (12) and (15), NRS 639.220(1) and/or NAC 639.702.

COUNT SEVEN
Pharmacy/Pharmacy Owner Responsibility
(Respondent American Wellness Pharmacy)

25. As the pharmacy/pharmacy owner at the time of the errors, omissions and violations alleged herein, Respondent American Wellness Pharmacy and/or Respondent's owners are responsible pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3) and subject to discipline pursuant to NRS 639.210(4), (11) and/or (12).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration and the pharmacy license of these Respondents.

Signed this 21st day of July 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMERICAN WELLNESS PHARMACY, Pharmacy License No. PH02705, and** **James Michael BARBER, RPH, Certificate of Registration No. 24357,** **Respondents.**	**Case Nos. 25-464-PH-S** **25-464-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 21st day of JULY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMERICAN WELLNESS PHARMACY, Pharmacy License No. PH02705,** **Respondent.**	**Case No. 25-464-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

AUTHORIZED REPRESENTATIVE FOR AMERICAN WELLNESS PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 31st day of July 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

American Wellness Pharmacy
2775 S Jones Blvd. Ste. 100A
Las Vegas, NV 89146

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
SEP 18 2026
NEVADA STATE BOARD OF PHARMACY

ANS
ANTHONY P. SGRO, ESQ.
Nevada Bar No. 3811
COLLEEN N. SAVAGE, ESQ.
Nevada Bar No. 14947
SGRO & ROGER
2901 El Camino Ave., Ste. 204
Las Vegas, Nevada 89102
Telephone: (702) 384-9800
Facsimile: (702) 665-4120
tsgro@sgroandroger.com
csavage@sgroandroger.com
Attorneys for American Wellness Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY Petitioner, v. AMERICAN WELLNESS PHARMACY, Pharmacy License No. PH02705, and JAMES MICHAEL BARBER, RPH, Certificate of Registration No. 24357, Respondents.	Case Nos. 25-464-PH-S 25-464-RPH-S **ANSWER TO PETITIONER'S NOTICE OF INTENDED ACTION AND ACCUSATION**

Respondent, AMERICAN WELLNESS PHARMACY ("AWP"), by and through undersigned counsel, ANTHONY P. SGRO, ESQ., and COLLEEN N. SAVAGE, ESQ., of the law firm of SGRO & ROGER, answers the Notice of Intended Action and Accusation ("Accusation") as follows. To the extent any allegation is not expressly admitted below, it is denied. AWP further reserves the right to amend or supplement this Answer and Notice of Defense as discovery proceeds, additional documentation is obtained, or the Accusation is amended.

Preliminary Statement

Every fact the Board now charges was known to the Board before it closed AWP's prior probation. The Board audited AWP in November 2025, investigated it in February–March 2026, and inspected it on April 1, 2026, all while AWP was on probation under Case No. 23-063-PH-S. The Board filed no charge during probation. Instead, it issued a Cease-and-Desist Order, supervised AWP's remediation, issued a Satisfaction of Order on June 23, 2026, confirming AWP had satisfied the prior Order, and issued AWP a clear, probation-free license on July 28, 2026. Only then, four weeks after certifying satisfaction, and days after issuing a clean license, did the Board file this Accusation on the same facts it had held all along.

AWP corrected the hazardous-drug facility conditions at the Board's direction; an independent laboratory certified the facility as passing on August 11, 2026; and the Board's own inspectors verified compliance on September 9, 2026. The prescription-level allegations in Counts 1 and 3 misstate the pharmacy's records. On these facts, the Accusation is barred or substantially limited by the parties' prior settlement, by preclusion principles, and by equitable estoppel, laches, and due process, and it fails on the merits.

Responses to Factual Allegations

Jurisdiction

1. AWP admits that at times relevant, it was a pharmacy licensed by the Board under License No. PH02705, and that Mr. Barber was a registered pharmacist. AWP admits the Board has jurisdiction to conduct disciplinary proceedings in the manner provided by law and otherwise denies any allegation inconsistent with the defenses below.

Factual Allegations

2. AWP admits that Case No. 23-063-PH-S was resolved by way of a Stipulation and Order entered September 4, 2024, and amended October 16, 2024, and January 15, 2025. AWP

affirmatively states that it satisfied that Order in full and received a Satisfaction of Order on June 23, 2026. AWP denies any characterization of the prior matter that is inconsistent with the Stipulation and Order and the Satisfaction of Order themselves.

3. AWP admits that Mr. Barber was employed as a managing pharmacist during the period alleged in the Accusation. AWP denies the remaining allegations contained in paragraph 3.

4. AWP denies the allegations contained in paragraph 4.

5. AWP denies the allegations contained in paragraph 5.

6. AWP states that prescriptions 6093041, 60954596, 6095471, 6095935, and 6096364 speak for themselves. AWP denies the remaining allegations contained in paragraph 6.

7. AWP states that prescriptions 6093041, 6094596, and speak for themselves. AWP denies the remaining allegations contained in paragraph 7.

8. AWP admits only that the Board conducted an inspection on April 1, 2026, and documented the facility conditions identified in the inspection. AWP denies any characterization of those conditions that is inconsistent with the Board's inspection records or applicable standards. Without admitting that the April 1, 2026, conditions constituted a violation warranting discipline, AWP affirmatively states that, upon service of the Cease-and-Desist Order, it immediately ceased hazardous-drug compounding; completed a comprehensive containment build-out; and obtained independent third-party certification on August 11, 2026, confirming that the facility satisfied all tested metrics. The Board's inspectors subsequently verified the facility's compliance on September 9, 2026. AWP therefore denies that it is presently out of compliance with USP 800. The prompt remediation and subsequent verification materially mitigate any sanction and undermine any claim that ongoing restrictions, suspension, or revocation are necessary to protect the public

9. AWP admits only that a cease-and-desist order was served on or about April 6, 2026, which speaks for itself. AWP alleges that it has complied with that order.

Responses to Applicable-Law Allegations

10. The allegations of paragraphs 10 through 18 state legal conclusions to which no response is required; to the extent a response is required, AWP denies that it violated any cited statute or regulation and denies that any cited provision supports discipline on these facts.

Responses to the Counts

Count One
Violations of Federal and State Law - Compounding Drug Products that are Essentially Copies of Commercially Available Drug Products Without a Statement of Significant Difference

19. AWP denies the allegations contained in paragraph 19.

Count Two
Violations of State Law - Filling Dangerous Drug Prescriptions Without an Original Signature from the Prescribing Practitioner

20. AWP denies the allegations contained in paragraph 20.

Count Three
Violations of Federal and State Law -Filling Controlled Substance Not Given by Electronic Transmission from the Prescribing Practitioner

21. AWP denies the allegations contained in paragraph 21.

Count Four
Violations of Federal and State Law- Compounding Sterile and Non-sterile Drug Products Out of Compliance with USP-800

22. AWP denies the allegations contained in paragraph 22.

Count Five
Unprofessional Conduct - Negligence in Compounding and Dispensing Drug Products

23. AWP denies the allegations contained in paragraph 23.

Count Six
Managing Pharmacist Responsibility

(Respondent Barber)

24. AWP is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies the allegations contained in paragraph 24.

Count Seven
Pharmacy/Pharmacy Owner Responsibility
(Respondent American Wellness Pharmacy)

25. AWP denies the allegations contained in paragraph 25.

Affirmative Defenses and Notice of Defense

26. The Accusation fails to state acts or omissions constituting grounds for discipline. An accusation must set forth the acts or omissions "in ordinary and concise language ...to the end that the respondent will be able to prepare a defense" and "must not consist merely of charges phrased in language of the statute or regulation." (NRS § 639.241)

27. AWP denies that Count Two is sufficiently supported because the Accusation does not identify the prescription(s) allegedly bearing a stamped signature.

28. The operative Stipulation and Order in Case No. 23-063-PH-S provides that AWP "shall have no new charges filed against American Wellness Pharmacy while on probation." Every factual predicate of this Accusation including the November 2025 audit, the February–March 2026 investigation, and the April 1, 2026, inspection, arose during that probation. The Board elected not to charge during probation, thereby avoiding the show-cause and stay-lifting mechanism it had bargained for; instead, it certified satisfaction and restored AWP's license with full knowledge of these facts. Having taken the benefits of that election, the Board should not be permitted to revive the withheld allegations after probation closed.

29. In the prior Stipulation and Order, "the Board and Respondent agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the

effective date of this Order." A release is construed under contract principles to effectuate the parties' intent, and a release of "any and all" claims, "known or unknown," reaches undiscovered claims existing at the time of the release. (*In re Amerco Derivative Litig.*, 127 Nev. 196, 252 P.3d 681 (2011)). To the extent any count rests on facts within the scope of the prior Accusation and existing on or before the prior Order's effective date, it is barred by the release.

30. A stipulated or consent order is a final judgment carrying claim-preclusive effect on the same claims or causes of action. (*Willerton v. Bassham, by Welfare Div., State, Dep't of Hum. Res.*, 111 Nev. 10, 889 P.2d 823 (1995)); (*Mendenhall v. Tassinari*, 133 Nev. 614, 403 P.3d 364 (2017)) Preclusion principles apply to administrative adjudications where the agency acts in a judicial capacity. (*Britton v. City of N. Las Vegas*, 106 Nev. 690, 799 P.2d 568 (1990)). The hazardous-drug facility conditions charged in Count Four are the same conditions the Board identified on April 1, 2026, and resolved through its April 6 and April 14, 2026, Cease-and-Desist Orders and the ensuing remediation under Case No. 23-063-PH-S, culminating in the June 23, 2026, Satisfaction of Order. Count Four impermissibly re-charges facts the Board already addressed and resolved.

31. Equitable estoppel lies against a governmental agency to avoid manifest injustice where (1) the party to be estopped was apprised of the true facts; (2) it intended its conduct to be acted upon, or so acted that the other party had a right to so believe; (3) the party asserting estoppel was ignorant of the true facts; and (4) it relied to its detriment. (*S. Nevada Mem'l Hosp. v. State, Dep't of Hum. Res.*, 101 Nev. 387, 705 P.2d 139 (1985)); (*State Indus. Ins. Sys. v. Giles,* 110 Nev. 216, 871 P.2d 920 (1994)). The rule barring estoppel against the government is confined to the sovereign asserting title to land and does not shield a licensing board that, with long-standing knowledge of the facts, delayed enforcement while the licensee built and invested in its practice.

(*Manning v. Nevada State Bd. of Acct.*, 99 Nev. 842, 673 P.2d 494 (1983)). The Board possessed every charged fact, issued a Satisfaction of Order and a clear license, and led AWP to proceed with a substantial hazardous-drug facility build-out in reliance. The elements of estoppel are met.

32. Laches bars a claim where there is inexcusable delay, knowledge by the party against whom laches is asserted, and resulting prejudice. (*State v. Rosenthal*, 107 Nev. 772, 819 P.2d 1296 (1991)); (*State ex rel. Dep't of Transp. v. Pub. Employees' Ret. Sys. of Nevada*, 120 Nev. 19, 83 P.3d 815 (2004)). The Board had knowledge of every charged fact no later than April 1, 2026, yet withheld charges until after probation closed and the license was cleared, prejudicing AWP, which reasonably treated the matters as resolved.

33. A professional license is a protected property interest, and due process guarantees of fundamental fairness apply to Board disciplinary proceedings. (*Burgess v. Storey Cnty. Bd. of Comm'rs*, 116 Nev. 121, 992 P.2d 856 (2000)); (*Dutchess Bus. Servs., Inc. v. Nevada State Bd. of Pharmacy*, 124 Nev. 701, 191 P.3d 1159 (2008)). Due process requires that a licensee be put on notice of the specific conduct charged and the standard alleged to have been violated. (*Burgess v. Storey Cnty. Bd. of Comm'rs*, 116 Nev. 121, 992 P.2d 856 (2000)); (*Nevada State Bd. of Pharmacy v. Garrigus*, 88 Nev. 277, 496 P.2d 748 (1972)). Charging AWP for conduct the Board long knew about, after certifying satisfaction and clearing the license, and pleading Count Three on a mismatched factual predicate, deprives AWP of fair notice and fundamental fairness.

34. AWP ceased hazardous-drug compounding, rebuilt the containment area, and installed an externally vented biological safety cabinet, with documented delays caused by the equipment manufacturer's shipping errors rather than any inaction by AWP. AWP's prompt cessation of hazardous-drug compounding, remediation, later certification, and the Board's subsequent

verification substantially mitigate any sanction and undermine any claim that ongoing restrictions, suspension, or revocation are necessary to protect the public.

35. A written dangerous-drug prescription must bear the practitioner's signature only "if the prescription was not transmitted orally." (NRS § 454.223). An electronically transmitted prescription need not contain the practitioner's signature where it bears a facsimile signature, security code, or unique mark, uses an approved biometric or voice-recognition system, or complies with NRS 439.581 to 439.597. (NRS § 639.2353). The handwritten-signature and original-form requirements of NAC 454.060 apply only to written prescriptions. (NAC 454.060). Count Two does not establish a violation as to prescriptions transmitted orally or electronically.

36. The requirement that controlled-substance prescriptions be electronically transmitted is subject to numerous exceptions, including technologic failure, a prescriber who also dispenses, prescriptions not supported by the electronic program, and circumstances where delay would adversely affect the patient, and violations are subject to administrative penalties. (NRS § 639.23535). Count Three neither pleads the absence of any exception nor as noted, identifies the correct supporting facts.

37. The grounds for discipline under (NRS § 639.210) are permissive, not mandatory. Even were any violation shown, the Board's sanction must reflect AWP's prompt and complete remediation, its substantial good-faith investment in compliance, and the favorable results of contemporaneous reviews by other regulators, including Nevada OSHA's closing conference with no citations proposed, and the NABP's acceptance of AWP's compliance. No suspension or revocation is warranted.

38. Investigation is ongoing, and AWP reserves the right to amend this Answer and to assert additional defenses as discovery and the record develop.

Objection To the Accusation

Pursuant to NRS 639.244(1)(a), AWP objects to the Accusation as incomplete and failing to set forth clearly the charges against it.

Request for Hearing and Relief

WHEREFORE, AWP requests that the Nevada State Board of Pharmacy:

1. Accept this Answer and Notice of Defense;

2. Set and conduct a hearing at which AWP may present evidence, witness testimony, and argument;

3. Consider AWP's evidence of remediation, compliance measures, current certification testing, and mitigation;

4. Dismiss the Accusation or, alternatively, decline to impose discipline against AWP; and

5. Grant such further relief as is just.

DATED this 18th day of September 2026.

SGRO & ROGER

/s/ Colleen Savage
ANTHONY P. SGRO, ESQ.
Nevada Bar No. 3811
COLLEEN N. SAVAGE, ESQ.
Nevada Bar No. 14947
Attorneys for American Wellness Pharmacy

Verification Pursuant to NRS 639.244(2)

I hereby declare, under penalty of perjury, that the foregoing Answer, and Affirmative Defense and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

/s/ George Maiorano
AMERICAN WELLNESS PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Sgro & Roger, and that on this 18th day of September 2026, I served a true and accurate copy of the foregoing document by electronic mail to the following:

Brett Kandt
General Counsel
Nevada State Board of Pharmacy
bkandt@pharmacy.nv.gov

/s/Caitlin Ferguson
Employee of Sgro & Roger

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

January 2018
Compounding

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

Additional copies are available from:
Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

January 2018
Compounding

TABLE OF CONTENTS

I. INTRODUCTION AND SCOPE 1
II. BACKGROUND 2
A. Section 503A of the FD&C Act 2
B. Compounding, Generally 2
C. Risks Associated with Compounded Drug Products 3
D. Compounded Drugs That Are Essentially Copies of Commercially Available Drug Products 3
III. POLICY 4
A. Commercially Available Drug Product 5
B. Essentially a Copy of a Commercially Available Drug Product 5
IV. PAPERWORK REDUCTION ACT 11
APPENDIX A. 12

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act
Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or the Agency) on this topic. It does not create any rights for any person and is not binding on FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed in the title page.

I. INTRODUCTION AND SCOPE

To qualify for exemptions under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a drug product must be compounded by a licensed pharmacist or physician who does not compound regularly or in inordinate amounts any drug products that are essentially copies of a commercially available drug product, among other conditions. This guidance sets forth FDA's policies regarding this provision of section 503A, including the terms *commercially available*, *essentially a copy of a commercially available drug product*, and *regularly or in inordinate amounts*.[2]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research, in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

[2] This guidance does not apply to drugs compounded for use in animals, to biological products subject to licensure in a biologics license application, or to repackaged drug products. For policies pertaining to mixing, diluting, and repackaging biological products, see FDA's guidance, *Mixing, Diluting, and Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.* For policies pertaining to repackaged drug products, see FDA's guidance, *Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities*.

All FDA guidances are available on the FDA guidance web page. FDA updates guidances regularly. To make sure you have the most recent version of a guidance, always consult the guidance web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

II. BACKGROUND

A. Section 503A of the FD&C Act

Section 503A, added to the FD&C Act by the Food and Drug Administration Modernization Act of 1997 and amended by the Drug Quality and Security Act in 2013, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to qualify for exemptions from the following three sections of the FD&C Act:[3]

- Section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP) requirements)
- Section 502(f)(1) (concerning the labeling of drugs with adequate directions for use)
- Section 505 (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs))

One of the conditions that must be met for a compounded drug product to qualify for the exemptions under section 503A of the FD&C Act is that it must be compounded by a licensed pharmacist or a licensed physician that "does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product."[4]

The statute further states that "the term 'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug."[5]

A complete list of the conditions that must be met for a compounded drug product to qualify for the exemptions in section 503A appears in the FDA guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*.

B. Compounding, Generally

Compounded drug products serve an important role for patients whose clinical needs cannot be met by an FDA-approved drug product, such as a patient who has an allergy and needs a medication to be made without a certain dye, an elderly patient who cannot swallow a pill and needs a medicine in a liquid form that is not otherwise available, or a child who needs a drug in a strength that is lower than that of the commercially available product. Drug products for identified individual patients can be compounded by licensed pharmacists in state-licensed

[3] In addition, under section 581(13) of the FD&C Act, the term "product," for purposes of pharmaceutical supply chain security requirements, does not include a drug compounded in compliance with section 503A.

[4] See section 503A(b)(1)(D).

[5] See section 503A(b)(2).

pharmacies and Federal facilities and by licensed physicians operating under section 503A of the FD&C Act. Drug products can also be compounded by outsourcing facilities under section 503B of the FD&C Act for identified individual patients pursuant to prescriptions or for distribution to health care practitioners without first receiving a prescription.[6] Both sections 503A and 503B restrict compounding drug products that are essentially a copy of a commercially available drug product (section 503A) or an approved drug product (section 503B).

C. Risks Associated with Compounded Drug Products

Although compounded drugs can serve an important need, they can also pose a higher risk to patients than FDA-approved drugs. Compounded drug products are not FDA-approved, which means they have not undergone FDA premarket review for safety, effectiveness, and quality. In addition, licensed pharmacists and licensed physicians who compound drug products in accordance with section 503A are not required to comply with CGMP requirements. Furthermore, FDA does not interact with the vast majority of licensed pharmacists and licensed physicians who compound drug products and seek to qualify for the exemptions under section 503A of the FD&C Act for the drug products that they compound because these compounders are not licensed by FDA and generally do not register their compounding facilities with FDA. Therefore, FDA is often not aware of potential problems with their compounded drug products or compounding practices unless it receives a complaint, such as a report of a serious adverse event or visible contamination.

FDA has investigated numerous serious adverse events associated with compounded drug products that were contaminated or otherwise compounded improperly, including the adverse events associated with the 2012 fungal meningitis outbreak in which contaminated injectable drug products resulted in more than 60 deaths and 750 cases of infection. FDA has also identified many pharmacies that compounded drug products under insanitary conditions such that the drug products may have been contaminated with filth or rendered injurious to health and that shipped the compounded drug products made under these conditions to patients and health care practitioners across the country, sometimes in large amounts.

D. Compounded Drugs That Are Essentially Copies of Commercially Available Drug Products

Section 503A provides exemptions from new drug approval, labeling with adequate directions for use, and CGMP requirements of the FD&C Act, so that drug products can be compounded as customized therapies for identified individual patients whose medical needs cannot be met by commercially available drug products. The restrictions on making drugs that are essentially copies ensure that pharmacists and physicians do not compound drug products under the exemptions for patients who could use a commercially available drug product. Such a practice would create significant public health risks because patients would be unnecessarily exposed to drug products that have not been shown to be safe and effective and that may have been prepared

[6] Section 503B of the FD&C Act describes the conditions that must be met for a human drug product compounded by an outsourcing facility to qualify for exemptions from sections 505, 502(f)(1), and 582 (concerning drug supply chain security requirements) of the FD&C Act. The conditions applicable to outsourcing facilities are discussed in separate guidances applicable to those facilities.

under substandard manufacturing conditions. FDA has investigated serious adverse events in patients who received contaminated compounded drugs when a comparable approved drug, made in a facility subject to CGMP requirements, was available.

In addition to these immediate public health risks, section 503A's limitations on producing a drug product that is essentially a copy of a commercially available drug product protects the integrity and effectiveness of the new drug and abbreviated new drug approval processes that Congress put in place to protect patients from unsafe, ineffective, or poor quality drugs. Furthermore, sponsors may be less likely to invest in and seek approval of innovative, life-saving medications if a compounder could, after a drug is approved, compound "substitutes" that may be less expensive because they have not had to demonstrate safety and effectiveness and are not produced in accordance with CGMP requirements or labeled with adequate directions for use.

Sponsors might also be less likely to seek approval of an ANDA for a generic drug if compounders were permitted to compound drugs that are essentially copies of commercially available drugs without going through the ANDA process. An ANDA must include data to demonstrate that the drug has the same active ingredient and is bioequivalent to an approved drug. FDA also conducts premarketing inspections of proposed manufacturing facilities.

The copies restriction also protects FDA's drug monograph process. FDA has an ongoing process for evaluating the safety and effectiveness of certain over-the-counter (OTC) medications, and if the Agency determines that an OTC drug meets certain conditions and is generally recognized as safe and effective, it will publish a final monograph specifying those conditions. Products that comply with a final monograph may be marketed, but manufacturers are required to meet CGMP standards. Restrictions in section 503A prevent compounders from producing drugs without having to comply with monograph standards, or CGMP requirements.

III. POLICY

As stated above, to qualify for the exemptions under section 503A of the FD&C Act, a drug must be compounded by a licensed pharmacist or a licensed physician that does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.[7] This means that a compounded drug product is not eligible for the exemptions in section 503A if it is (1) essentially a copy of a commercially available drug product, and (2) compounded regularly or in inordinate amounts. Accordingly, and as discussed below, when evaluating whether a drug product meets the condition in section 503A regarding essentially copies, FDA intends to determine whether a compounded drug product is *essentially a copy of a commercially available drug product:* if it is, FDA intends to determine whether the drug product was compounded regularly or in inordinate amounts.[8]

[7] See section 503A(b)(1)(D).

[8] FDA is considering the applicability of the policies described in this guidance to hospitals and health systems and intends to address these issues in separate guidance or rulemaking. FDA regards a health system as collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients. There is no definition of "health system" that applies to all sections of the FD&C Act.

FDA's policies with regard to the terms (1) *commercially available drug product*, (2) *essentially a copy of a commercially available drug product*, and (3) *regularly or in inordinate amounts*, are as follows:

A. Commercially Available Drug Product

For purposes of this guidance, a drug product is commercially available if it is a marketed drug product.

We do not consider a drug product to be commercially available if

- the drug product has been discontinued and is no longer marketed[9] or
- the drug product appears on the FDA drug shortage list in effect under section 506E of the FD&C Act.[10] A drug "appears on the drug shortage list in effect under section 506E" if the drug is in "currently in shortage" status (and not in "resolved" status) in FDA's drug shortage database.

Commercially available drugs are available on the market, and they are generally subject to FD&C Act requirements relating to approval, labeling, and CGMP requirements, and the copies restriction applies to all such drugs because section 503A is not intended to provide a means for compounders to produce compounded drugs exempt from the Act's requirements that are essentially copies of commercially available drug products.

B. Essentially a Copy of a Commercially Available Drug Product

1. What is Essentially a Copy?

FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if:

- the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product;
- the API(s) have the same, similar, or an easily substitutable dosage strength; and

---

However, this is the definition of a "health system" used in section 506F of the Act concerning hospital repackaging of drugs in shortage.

[9] FDA maintains a list of approved drug products that sponsors have indicated are not marketed in the discontinued section of the list of Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). See http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Specifically, the list includes approved drug products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined were withdrawn for safety or effectiveness reasons, or have had their approvals withdrawn for reasons other than safety or effectiveness subsequent to being discontinued from marketing.

[10] See http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

- the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug,

unless, as provided by section 503A(b)(2), a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product.

The limitations in section 503A(b)(1)(D) apply to the compounding of drug products that are *essentially* copies of a commercially available drug product – not only to drugs that are exact copies or even to drugs that are nearly identical. This is to ensure that compounders do not evade the limits in this section by making relatively small changes to a compounded drug product and then offering the drug to the general public without regard to whether a prescribing practitioner has determined that the change produces for the patient a significant difference. For example, Congress contemplated that a compounded drug may be essentially a copy of a commercially available drug if "minor changes in strength (such as from .08% to .09%) are made that are not known to be significant . . ." for the patient for whom the drug was prescribed.[11]

a. Same API

With regard to the characteristics listed above, an API is the substance in a drug product that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body.[12] When a compounded drug product offers the same API as a commercially available drug product, in the same, similar, or easily substitutable dosage strength and for use through the same route of administration, we generally intend to consider such a drug product *essentially a copy*, unless a prescriber determines that there is a change, made for an identified individual patient, that will produce a significant difference for that patient.

We recognize that, for some patients, a drug product that has the same API, strength, and route of administration may include a change that produces a significant difference for a particular patient. For example, a drug product compounded without a particular inactive ingredient may produce a significant difference for a patient who has an allergy to the inactive ingredient in the commercially available drug product. However, for other patients, this change may produce no difference at all. Congress did not intend for compounders to use, for example, the fact that some patients may have allergies as a basis to compound a drug without the inactive ingredient for other patients who do not have the allergy under the exemptions in section 503A (i.e., without meeting requirements for premarket approval, labeling with adequate directions for use, or

[11] U.S. House. Food and Drug Administration Modernization Act of 1997, *Conference Report* (to Accompany S. 830). (105 H. Rpt. 399).

[12] Section 503A refers to bulk drug substances. A *bulk drug substance* is defined as any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. It does not include intermediates used in the synthesis of the substance. This definition is the same as the definition of active pharmaceutical ingredient. See 21 CFR 207.1, 207.3.

CGMP requirements).[13] In the context of compounding and consistent with the statute, we generally intend to consider such a drug essentially a copy unless a prescriber determines that there is a change that will produce a significant difference for the patient for whom it is prescribed.

b. Same, Similar or Easily Substitutable Strength

FDA generally intends to consider two drugs to have a similar dosage strength if the dosage strength of the compounded drug is within 10% of the dosage strength of the commercially available drug product.

With regard to the concept of easily substitutable strength, in some cases, the same or similar dosage strength can be achieved by administration of fractional or multiple doses of a drug product. For example, if FDA-approved Drug X tablets have a dosage strength of 25 mg and a patient needs 50 mg of Drug X, FDA would generally consider a compounded Drug X 50 mg tablet to have an easily substitutable strength because the patient could take two Drug X 25 mg tablets to achieve the required dose.[14]

c. Same Route of Administration

Route of administration is a way of administering a drug to a site in a patient (e.g., topical, intravenous, oral).[15] In general, FDA does not intend to consider a compounded drug product with the same API and similar or easily substitutable strength to be essentially a copy of a commercially available drug product if the compounded drug product and the commercially available drug product have different routes of administration (e.g., if the commercially available drug product is oral and the compounded drug product is topical). However, if the compounded drug product has the same API and similar or easily substitutable strength as the commercially available drug product and the commercially available drug product can be used (regardless of how it is labeled) by the route of administration prescribed for the compounded drug, FDA generally intends to consider the compounded drug to be essentially a copy of the commercially available drug. In this case, the compounded drug product generally would not produce a significant difference for an identified individual patient relative to the commercially available drug product.

For example, if the commercially available drug is an injectable drug sold in a vial that is labeled for intra-muscular use, but the drug also can be drawn from the vial by a smaller needle for subcutaneous administration, a compounded drug product with the same API and similar or

[13] *See* note 11.

[14] If a commercially available tablet must be split to achieve the prescribed dosage strength, and such tablet is not suitable for splitting, FDA would not consider the compounded drug made to the prescribed dosage strength to have an easily substitutable strength. For example, some tablets may be too small or crumble too easily when split, making splitting an inappropriate option. Information regarding tablet splitting may be printed in the "HOW SUPPLIED" section of the professional label insert and in the patient package insert of an approved drug product.

[15] See http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071667.htm.

easily substitutable strength prescribed for sub-cutaneous administration would generally be considered to be essentially a copy, unless the prescriber documents on the prescription that the compounded drug product produces a significant difference for the identified individual patient.

d. Same Characteristics as Two or More Commercially Available Drug Products

FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if the compounded drug product contains the same APIs as two or more commercially available drug products in the same, similar, or easily substitutable strength and if the commercially available drug products can be used (regardless of how they are labeled) by the same route of administration prescribed for the compounded drug, unless there is documentation as described in section III.B.2. Such drug products present the same kinds of concerns as drug products that have a single API and in some respects may be more dangerous because of the potential for unintended drug interactions or formulation issues. For example, if drug X and drug Y are commercially available oral drug products, FDA generally intends to consider a compounded oral drug product that combines drug X and drug Y in strengths that are within 10% of the strengths of the respective commercially available products to be essentially a copy of the commercially available drug product, unless a prescriber determination of a significant difference has been documented.

2. Statement of Significant Difference

Pursuant to section 503A(b)(2) of the FD&C Act, a compounded drug product is not essentially a copy of a commercially available drug product if a change is made for an identified individual patient, and the prescribing practitioner has determined that the change will produce a significant difference for that patient. If a compounder intends to rely on such a determination to establish that a compounded drug is not essentially a copy of a commercially available drug product, the compounder should ensure that the determination is documented on the prescription.

FDA does not believe that a particular format is needed to document the determination, provided that the prescription makes clear that the prescriber identified the relevant change and the significant difference that the change will produce for the patient. For example, the following would be sufficient:

- "No Dye X, patient allergy" (if the comparable drug contains the dye)
- "Liquid form, patient can't swallow tablet" (if the comparable drug is a tablet)
- "6 mg, patient needs higher dose" (if the comparable drug is only available in 5 mg dose)

However, if a prescription identifies only a patient name and drug product formulation, this would not be sufficient to establish that the prescriber made the determination described by section 503A(b)(2). Note also that the significant benefit that the prescriber identifies must be produced by the change the compounder will make to a commercially available drug product (i.e., a change in drug product formulation). Other factors, such as a lower price, are not

sufficient to establish that the compounded drug product is not essentially a copy of the commercially available drug product.[16]

If a prescription does not make clear that the prescriber made the determination required by section 503A(b)(2), or a compounded drug is substituted for the commercially available drug product, the compounder can contact the prescriber and if the prescriber confirms it, make a notation on the prescription that the compounded drug product contains a change that makes a significant difference for the patient. The notations should be as specific as those described above, and the date of the conversation with the prescriber should be included on the prescription.[17]

It is not possible to offer exhaustive guidance about when a difference will be "significant" to an identified individual patient. At this time, FDA generally does not intend to question prescriber determinations that are documented in a prescription or notation. However, we do intend to consider whether a prescription or notation relied upon by a compounder to establish that a drug is not essentially a copy documents that the determination was made.

If the compounder produces drugs in anticipation of receiving valid prescriptions for identified individual patients, and the compounder obtains the statement of significant difference from the prescriber when it receives the prescription for the compounded drug, prior to distribution, FDA does not intend to consider the compounded drug that is then distributed to be essentially a copy.

3. Documentation of Shortage

If the drug was compounded because the approved drug product was not commercially available because it was on the FDA drug shortage list, the prescriber or compounder should include a notation on the prescription that it was on the drug shortage list and the date the list was checked.[18]

4. Regularly or in Inordinate Amounts

A drug product is not eligible for the exemptions in section 503A if it is prepared by a pharmacist or physician who compounds "regularly or in inordinate amounts (as defined by the Secretary)" any drug products that are essentially copies of a commercially available drug

[16] Congress noted that "where it is readily apparent, based on the circumstances, that the 'significant difference' is a mere pretext to allow compounding of products that are essentially copies of commercially available products, such compounding would be considered copying of commercially available products and would not qualify for the compounding exemptions if it is done regularly or in inordinate amounts. Such circumstances may include, for example, instances in which minor changes in strength (such as from .08% to .09%) are made that are not known to be significant or instances in which the prescribing physician is receiving financial remuneration or other financial incentives to write prescriptions for compounded products." *See* the U.S. House. Food and Drug Administration Modernization Act of 1997, *Conference Report* (to Accompany S. 830). (105 H. Rpt. 399).

[17] See section IV of this guidance.

[18] See section IV of this guidance.

product.[19] FDA interprets this to mean that, in order to be compounded in accordance with section 503A, a drug product that is essentially a copy of a commercially available drug product cannot be compounded regularly – i.e., it cannot be compounded at regular times or intervals, usually, or very often. Nor can the amounts compounded be inordinate, in light of the purpose of section 503A.

Section 503A is intended to protect patients from the public health risks of providing compounded drugs to patients whose medical needs could be met by commercially available drug products and to protect the integrity and efficiency of the drug approval process. Under the statutory scheme, only very rarely should a compounded drug product that is essentially a copy of a commercially available drug product be offered to a patient. We conclude, therefore, that a drug product that is essentially a copy of a commercially available drug product is compounded regularly or in inordinate amounts if it is compounded more frequently than needed to address unanticipated, emergency circumstances, or in more than the small quantities needed to address unanticipated, emergency circumstances.

It is important to note that the regularly or in inordinate amounts provision is not implicated if the compounded drug is not essentially a copy of a commercially available drug product. For example, a compounded drug product that has the same API, dosage strength, and route of administration as a drug product on FDA's shortage list would not be considered essentially a copy of a commercially available drug because a drug product is not considered *commercially available* if it is on FDA's drug shortage list. In addition, a compounded drug product is not essentially a copy of a commercially available drug product if a prescriber has determined that the compounded drug has a change that produces a significant difference for a patient.
Once it has been determined that a compounded drug is essentially a copy of a commercially available drug product as described above, the following are examples of factors that may be the basis for concluding that it has been compounded regularly or in inordinate amounts:

- The compounded drug product amounts to more than a small number of prescriptions or a small percentage of the compounded drug products that a compounder prepares.
- The compounder routinely substitutes compounded drugs that are essentially copies of commercially available drugs upon receiving prescriptions for patients.
- The compounder offers pre-printed prescription pads that a prescriber can use to write a prescription for the drug product that is essentially a copy without making a determination that there is a change that will produce a significant difference for a patient.
- The compounded drug product is not compounded on an as-needed basis, but on a routine or pre-set schedule.

The foregoing list is not intended to be exhaustive. Other factors may be appropriate for consideration in a particular case.

To focus enforcement on the most significant cases, as a matter of policy, at this time FDA does not intend to take action against a compounder for compounding a drug product that is

[19] See section 503A(b)(1)(D).

essentially a copy of a commercially available drug product regularly or in inordinate amounts if the compounder fills four or fewer prescriptions for the relevant compounded drug product in a calendar month.[20] As noted above, a compounded drug product is not essentially a copy of a commercially available drug product if a prescriber has determined that the compounded drug has a change that produces a significant difference for a patient; thus, a prescription that documents such a prescriber determination would not be counted towards the four prescriptions.

Compounders may produce a limited amount of drugs in anticipation of receiving valid prescriptions for identified individual patients. See section 503A(a)(2). FDA generally intends to consider whether such drugs are essentially a copy at the time the drug is distributed rather than the time it is produced.

5. Recordkeeping

A licensed pharmacist or physician seeking to compound a drug product under section 503A should maintain records to demonstrate compliance with section 503A(b)(1)(D). For example, records should be kept of notations on prescriptions for identified individual patients that a prescriber has determined that the compounded drug has a change that produces a significant difference for the identified patient.

Compounders under section 503A should also maintain records of the frequency in which they have compounded drug products that are essentially copies of commercially available drug products and the number of prescriptions that they have filled for compounded drug products that are essentially copies of commercially available drug products to document that such compounding has not been done regularly or in inordinate amounts.[21]

FDA recommends that compounders maintain the records described above for a period of at least three years.

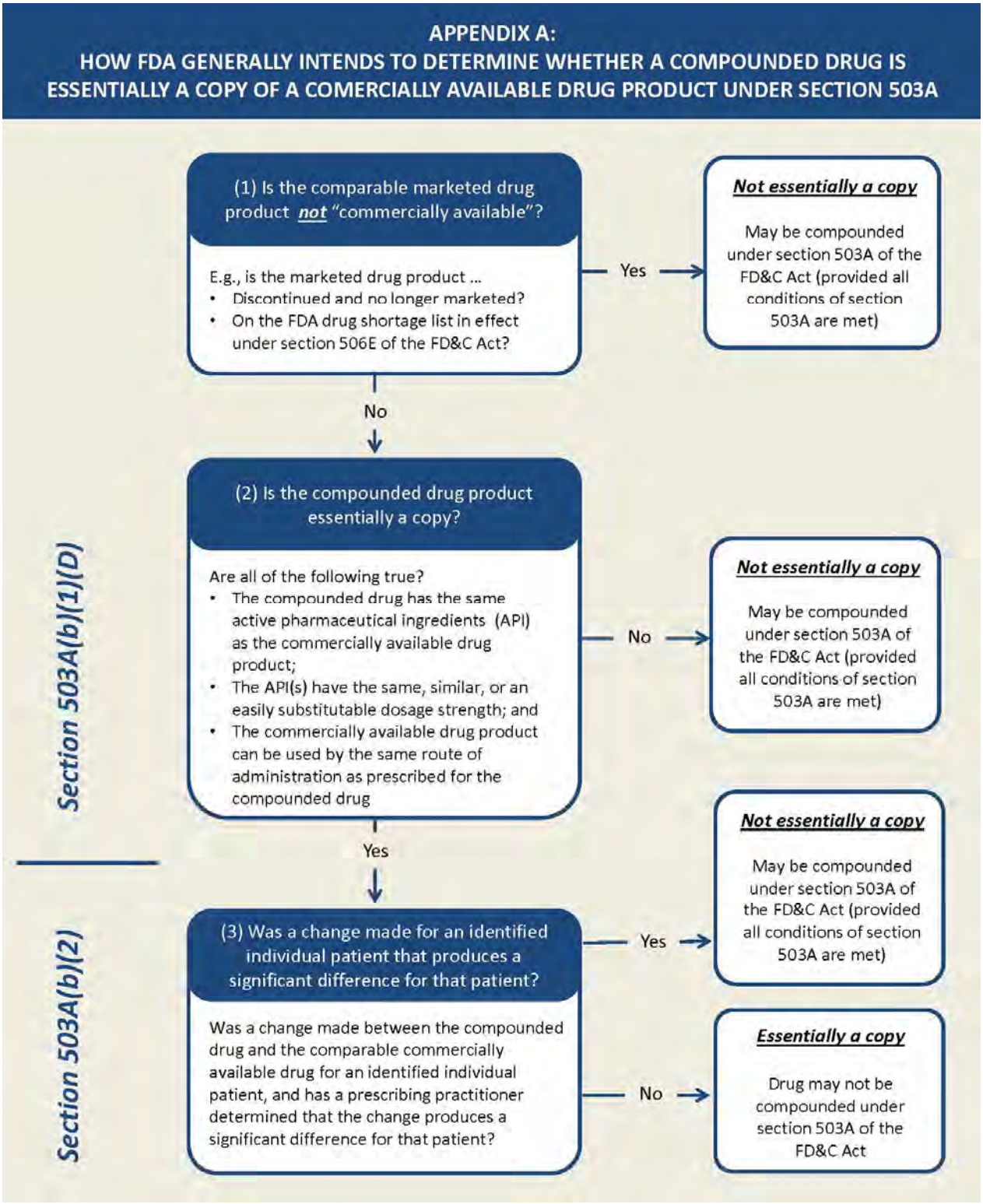
IV. PAPERWORK REDUCTION ACT

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). See footnotes 17, 18, and 21. These provisions require review and are not in effect until they display a currently valid OMB control number. The information collection provisions in this guidance have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. FDA will publish a notice in the *Federal Register* announcing OMB's decision regarding the information collection provisions in this guidance.

[20] For purposes of this policy, FDA intends to consider each refill of a prescription as an additional prescription.

[21] See section IV of this guidance.

APPENDIX A.


APPENDIX A:
HOW FDA GENERALLY INTENDS TO DETERMINE WHETHER A COMPOUNDED DRUG IS ESSENTIALLY A COPY OF A COMERCIALLY AVAILABLE DRUG PRODUCT UNDER SECTION 503A
(1) Is the comparable marketed drug product not "commercially available"?
E.g., is the marketed drug product ...
• Discontinued and no longer marketed?
• On the FDA drug shortage list in effect under section 506E of the FD&C Act?
Yes
Not essentially a copy
May be compounded under section 503A of the FD&C Act (provided all conditions of section 503A are met)
No
Section 503A(b)(1)(D)
(2) Is the compounded drug product essentially a copy?
Are all of the following true?
• The compounded drug has the same active pharmaceutical ingredients (API) as the commercially available drug product;
• The API(s) have the same, similar, or an easily substitutable dosage strength; and
• The commercially available drug product can be used by the same route of administration as prescribed for the compounded drug
No
Not essentially a copy
May be compounded under section 503A of the FD&C Act (provided all conditions of section 503A are met)
Yes
Section 503A(b)(2)
(3) Was a change made for an identified individual patient that produces a significant difference for that patient?
Was a change made between the compounded drug and the comparable commercially available drug for an identified individual patient, and has a prescribing practitioner determined that the change produces a significant difference for that patient?
Yes
Not essentially a copy
May be compounded under section 503A of the FD&C Act (provided all conditions of section 503A are met)
No
Essentially a copy
Drug may not be compounded under section 503A of the FD&C Act

5L

FILED
JUL 2 1 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

AMERICAN WELLNESS PHARMACY, Pharmacy License No. PH02705, and

JAMES MICHAEL BARBER, RPH, Certificate of Registration No. 24357,

Respondents.

CASE NOS. 25-464-PH-S
25-464-RPH-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent James Michael Barber, RPh (Barber), Certificate of Registration No. 24357, was a pharmacist registered with the Board, and Respondent American Wellness Pharmacy, Pharmacy License No. PH02705, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Respondent American Wellness Pharmacy has a record of prior discipline from the Board in case no. 23-063-PH-S, a stipulated settlement entered September 4, 2024, and amended October 16, 2024, and January 15, 2025, arising from Respondent's compounding and dispensing drug products in violation of NAC 639.661-.690, *inclusive*, and related federal law, 21 U.S.C. § 353a.

3. Barber was employed as managing pharmacist by American Wellness Pharmacy at the time of the events alleged herein.

4. Board staff determined during an inspection/audit in November 2025 that Respondents compounded and dispensed sterile injectable drug products to patients in Nevada that were essentially copies of tirzepatide while the drug product was commercially available, and without a "statement of significant difference" for each prescription documenting a medical need specific to the patient for the compounded product, including, without limitation, the following prescriptions for tirzepatide w/ B6 12-0.1 mg/ml 1ml vial injection:

Prescription No. 6091671: patient J.P.; issued 9/22/25 and dispensed 9/25/25

Prescription No. 6091666: patient M.K.; issued 9/22/25 and dispensed 9/25/25

Prescription No. 6091767: patient M.G.; issued 9/24/25 and dispensed 9/25/25

Prescription No. 6092002: patient J.T.; issued 9/30/25 and dispensed 9/30/25

Prescription No. 6092081: patient E.B.; issued 10/1/25 and dispensed 10/1/25

5. During that inspection/audit Board staff also determined that Respondents accepted and filled dangerous drug prescriptions with a stamped signature from the practitioner.

6. Board staff subsequently determined during an investigation in February-March 2026 that Respondents compounded and dispensed additional drug products to patients in Nevada that were essentially copies of commercially available drug products without a "statement of significant difference" for each prescription, including, without limitation, the following prescriptions:

Prescription No. 6093041: patient A.T. from practitioner A.F.; verbally transcribed 10/22/25 for "testosterone cypionate 200mg/ml in MCT oil"

Prescription No. 6094596: patient A.Z. from practitioner R.T.; verbally transcribed for 11/25/25 for "testosterone 50mg/ml"

Prescription No. 6095471: patient S.S. issued electronically 12/12/25 for "tirzepatide-l carnitine12-100 mg/ml INJECTION"

Prescription No. 6095935: patient M.F. issued electronically 12/26/25 for "tirzepatide-l carnitine 12-100 mg/ml injectable"

Prescription No. 6096364: patient M.R. issued electronically 1/6/26 for "testosterone cypionate 50mg/ml" with directions to "compound in grape seed oil"

7. During that investigation Board staff also determined that Respondents accepted and filled controlled substance prescriptions given by oral order from the practitioner, including, without limitation, the following prescriptions:

Prescription No. 6093041: patient A.T. from practitioner A.F.; verbally transcribed 10/22/25 for "testosterone cypionate 200mg/ml in MCT oil"

Prescription No. 6094596: patient A.Z. from practitioner R.T.; verbally transcribed for 11/25/25 for "testosterone 50mg/ml"

Prescription No. 6097319: patient MC. From practitioner J.N.; verbally transcribed 1/23/26 for "testosterone cyp 50mg/ml"

8. On April 1, 2026, Board inspectors conducting an inspection determined that Respondents were compounding sterile and non-sterile drug products out of compliance with chapter 800 of the *United States Pharmacopeia - National Formulary* (USP-800) as follows:

A. The location stores HD API products for non-sterile compounding in a room that is neutral pressure to surrounding areas, is not externally ventilated, and has never been tested for air exchanges per hour. Per USP-800 guidelines all HD API's must be stored in a room that is externally ventilated, has negative pressure to surrounding areas, and has at least 12 air exchanges per hour.

B. The location stores HD API products for sterile compounding in a room that is positive pressure to surrounding areas and is not externally ventilated. See comment #1 for USP-800 requirements.

C. The location compounds non-sterile HD API products in a hood located in a separate room from the retail and sterile compounding area. The room would be defined as the C-SEC (containment secondary engineering control). The room used for non-sterile hazardous

compounding is not externally vented, has never been tested for air exchanges per hour, and is neutral pressure compared to surrounding areas. Per USP-800 guidelines the room must be externally vented, have at least 12 air exchanges per hour, and have a negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas.

D. The location compounds sterile HD API products in a hood located in an ISO-7 classified buffer room. The room is not externally vented and is positive pressure in relation to adjacent areas. Per USP-800 guidelines the room must be externally vented and have a negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas.

E. The location compounds sterile HD API products in a biological safety cabinet that has been certified by an outside agency. The BSC is located in an ISO-7 classified buffer room. The BSC is not externally vented. Per USP-800 guidelines the BSC must be externally vented.

F. The location compounds sterile HD API products in an ISO-7 classified buffer room. The adjacent ante room is an ISO-8 classified ante room. Per USP -800 guidelines the ante room for sterile hazardous compounding must be an ISO-7 classified area.

9. On or about April 6, 2026, Board staff served Respondents with an order to cease-and-desist compounding sterile and non-sterile drug products in violation of chapter 800 of the United States Pharmacopeia - National Formulary (USP-800).

APPLICABLE LAW

10. A pharmacy engaged in the practice of compounding drug products and dispensing compounded drug products in Nevada shall comply with the provisions of NAC 639.661 -.690, *inclusive*, as amended by LCB File No. R053-24, and related federal law, 21 U.S.C. § 353a, the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishing national standards for compounding medications. This includes, without limitation, compliance with chapter 800 of the *United States Pharmacopeia - National Formulary* (USP-800) as applicable.

11. Federal law prohibits compounding a drug product that is essentially a copy of a commercially available product. 21 U.S.C. § 353a(b)(1)(D). Pursuant to section 503A(b)(2) of

the FD&C Act (21 U.S.C. § 353a(b)(2)), a compounded drug product is not essentially a copy of a commercially available drug product if a change is made for an identified individual patient, and the prescribing practitioner has determined that the change will produce a significant difference for that patient. If a compounder intends to rely on such a determination to establish that a compounded drug is not essentially a copy of a commercially available drug product, the compounder should ensure that the determination is documented on the prescription in a "statement of significant difference."

12. A written prescription for a dangerous drug must contain in pertinent part the original handwritten signature of the prescribing practitioner in nonerasable ink. NRS 454.223(2)(a); NRS 639.2353(2)(a); NAC 454.060.

13. A prescription for a controlled substance must be given to a pharmacy by electronic transmission in accordance with the regulations adopted by the Board. NRS 639.23535(1); 21 CFR Part 1311.

14. Performing any duties as the holder of a license or registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

15. The Board may suspend or revoke a license or registration if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

16. The Board may suspend or revoke a license or registration if the holder has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

17. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the

pharmacy and the practice of pharmacy, including recordkeeping. NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.

18. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of a pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violations of Federal and State Law – Compounding Drug Products that are Essentially Copies of Commercially Available Drug Products Without a Statement of Significant Difference

19. By compounding drug products to patients in Nevada that were essentially copies of commercially available drug products, as alleged in paragraphs 4 and 6 herein, Respondents and/or Respondents' personnel violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 353a(b)(1)(D) and Section 3 of LCB File No. R053-24, and Respondents are therefore subject to discipline pursuant to NRS 639.210(11), (12) and (15), NRS 639.220(1), NRS 639.230(5), NAC 639.702, and/or NAC 639.945(3).

COUNT TWO

Violations of State Law – Filling Dangerous Drug Prescriptions Without an Original Signature from the Prescribing Practitioner

20. By filling and dispensing dangerous drug prescriptions with a stamped signature from the practitioner, as alleged in paragraph 5 herein, Respondents and/or Respondents' personnel violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.223(2)(a), NRS 639.2353(2)(a) and/or NAC 454.060, and Respondents are therefore subject to discipline pursuant to NRS 639.210(11), (12) and (15), NRS 639.220(1), NRS 639.230(5), NAC 639.702, and/or NAC 639.945(3).

COUNT THREE

Violations of Federal and State Law – Filling Controlled Substance Not Given by Electronic Transmission from the Prescribing Practitioner

21. By filling and dispensing controlled substance prescriptions given by oral order from the practitioner, as alleged in paragraph 5 herein, Respondents and/or Respondents' personnel violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.23535(1) and/or 21 CFR Part 1311, and Respondents are therefore subject to discipline pursuant to NRS 639.210(11), (12) and (15), NRS 639.220(1), NRS 639.230(5), NAC 639.702, and/or NAC 639.945(3).

COUNT FOUR

Violations of Federal and State Law – Compounding Sterile and Non-sterile Drug Products Out of Compliance with USP-800

22. By compounding sterile and non-sterile drug products out of compliance with USP-800, as alleged in paragraph 8 herein, Respondents and/or Respondents' personnel violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NAC 639.661 - .690, *inclusive*, as amended by LCB File No. R053-24, and related federal law, 21 U.S.C. § 353a, and Respondents are therefore subject to discipline pursuant to NRS 639.210(11), (12) and (15), NRS 639.220(1), NRS 639.230(5), NAC 639.702, and/or NAC 639.945(3).

COUNT FIVE

Unprofessional Conduct – Negligence in Compounding and Dispensing Drug Products

23. By their acts as alleged herein, Respondents and/or Respondents' personnel engaged in unprofessional conduct as defined in NAC 639.945(1)((i), and Respondents are therefore subject to discipline pursuant to NRS 639.210(4), NRS 639.220(1), NRS 639.230(5), NAC 639.702, and/or NAC 639.945(3).

COUNT SIX

Managing Pharmacist Responsibility (Respondent Barber)

24. As the managing pharmacist of Respondent American Wellness Pharmacy at the time of the errors, omissions and violations alleged herein, Respondent Barber is responsible and

subject to discipline pursuant to NRS 639.210(4), (11), (12) and (15), NRS 639.220(1) and/or NAC 639.702.

COUNT SEVEN

Pharmacy/Pharmacy Owner Responsibility
(Respondent American Wellness Pharmacy)

25. As the pharmacy/pharmacy owner at the time of the errors, omissions and violations alleged herein, Respondent American Wellness Pharmacy and/or Respondent's owners are responsible pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3) and subject to discipline pursuant to NRS 639.210(4), (11) and/or (12).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration and the pharmacy license of these Respondents.

Signed this 21st day of JULY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMERICAN WELLNESS PHARMACY, Pharmacy License No. PH02705, and** **James Michael BARBER, RPH, Certificate of Registration No. 24357,** **Respondents.**	**Case Nos. 25-464-PH-S** **25-464-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 21st day of JULY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JAMES MICHAEL BARBER, RPH, Certificate of Registration No. 24357,** **Respondent.**	**Case No. 25-464-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

JAMES MICHAEL BARBER, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 31st day of July 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

James Barber, RPh
[redacted]
Las Vegas, NV [redacted]

James Barber, RPh
c/o American Wellness Pharmacy
2775 S Jones Blvd. Ste. 100A
Las Vegas, NV 89146

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AMERICAN WELLNESS PHARMACY, Pharmacy License No. PH02705, and** **JAMES MICHAEL BARBER, RPH, Certificate of Registration No. 24357,** **Respondents.**	**CASE NOS. 25-464-PH-S** **25-464-RPH-S** **STIPULATION AND ORDER [RESPONDENT BARBER ONLY]**

J. David Wuest, in his capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent James Michael Barber, RPh (Barber), Certificate of Registration No. 24357, **HEREBY STIPULATE AND AGREE THAT**:

1. On or about July 31, 2026, Respondent Barber was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing. Respondent is entering this Stipulation in lieu of filing an Answer and Notice of Defense to the Accusation.

2. Respondent is fully aware of the right to seek the advice of counsel in this matter prior to entering into this Stipulation.

3. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

4. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with

the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. The allegation in Paragraph 7 of the Accusation is withdrawn and the related cause of action against Respondent as set forth in Count Three, Paragraph 21 of the Accusation, is hereby DISMISSED pursuant to NRS 622A.320(4).

6. Respondent Barber does not contest the remaining allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. By compounding drug products to patients in Nevada that were essentially copies of commercially available drug products, Respondents and/or Respondents' personnel violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 353a(b)(1)(D) and Section 3 of LCB File No. R053-24, and Respondents are therefore subject to discipline pursuant to NRS 639.210(11), (12) and (15), NRS 639.220(1), NRS 639.230(5), NAC 639.702, and/or NAC 639.945(3).

B. By filling and dispensing dangerous drug prescriptions with a stamped signature from the practitioner, Respondents and/or Respondents' personnel violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.223(2)(a), NRS 639.2353(2)(a) and/or NAC 454.060, and Respondents are therefore subject to discipline pursuant to NRS 639.210(11), (12) and (15), NRS 639.220(1), NRS 639.230(5), NAC 639.702, and/or NAC 639.945(3).

C. By compounding sterile and non-sterile drug products out of compliance with USP-800, Respondents and/or Respondents' personnel violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NAC 639.661 -.690, *inclusive*, as amended by LCB File No. R053-24, and related federal law, 21 U.S.C. § 353a, and Respondents are therefore

subject to discipline pursuant to NRS 639.210(11), (12) and (15), NRS 639.220(1), NRS 639.230(5), NAC 639.702, and/or NAC 639.945(3).

D. By their acts Respondents and/or Respondents' personnel engaged in unprofessional conduct as defined in NAC 639.945(1)((i), and Respondents are therefore subject to discipline pursuant to NRS 639.210(4), NRS 639.220(1), NRS 639.230(5), NAC 639.702, and/or NAC 639.945(3).

E. As the managing pharmacist of Respondent American Wellness Pharmacy, Pharmacy License No. PH02705, at the time of the errors, omissions and violations alleged herein, Respondent Barber is responsible and subject to discipline pursuant to NRS 639.210(4), (11), (12) and (15), NRS 639.220(1) and/or NAC 639.702.

7. Those violations are pled with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

8. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Barber stipulate to the following penalties. Respondent James Michael Barber, RPh, Certificate of Registration No. 24357, is placed on probation pursuant to NRS 639.255(1)(b) for a period of one (1) year subject to the following conditions:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Barber shall pay a fine of Two Thousand Dollars ($2000.00) for the violations, by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 4, 2026;

B. Pursuant to NRS 622.400, Barber shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for recoverable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 4,2026;

C. Barber shall not work as managing pharmacist of any compounding pharmacy licensed by the Board while on probation;

D. Barber shall not engage in the practice of compounding sterile drug products unless and until he completes twenty (20) extra hours of continuing education (CE) on sterile compounding, in addition to the CE hours he must otherwise complete to maintain licensure, and provides certificates demonstrating completion to the Board;

E. Barber shall complete ten (10) extra hours of continuing education (CE) on nonsterile compounding, in addition to the CE hours he must otherwise complete to maintain licensure, and provide certificates demonstrating completion to the Board; and

F. While on probation, Barber shall comply with all federal and state statutes and regulations regarding controlled substances, dangerous drugs, and the practice of pharmacy, shall have no additional administrative charges filed by the Board, and shall have no action taken that would be reportable pursuant to NAC 639.229.

Upon successful completion of probation, Respondent's Certificate of Registration No. 24357 will be fully restored.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 14, 2026. Respondent will appear in person at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of _____ 2026

JAMES MICHAEL BARBER, RPH
Certificate of Registration No. 24357

Signed this ___ day of _____ 2026

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent James Michael Barber, RPh, Certificate of Registration No. 24357, in Case No. 25-464-RPH-S, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of October 2026.

_____
Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

January 2018
Compounding

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

Additional copies are available from:
Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

January 2018
Compounding

TABLE OF CONTENTS

I. INTRODUCTION AND SCOPE 1
II. BACKGROUND 2
A. Section 503A of the FD&C Act 2
B. Compounding, Generally 2
C. Risks Associated with Compounded Drug Products 3
D. Compounded Drugs That Are Essentially Copies of Commercially Available Drug Products 3
III. POLICY 4
A. Commercially Available Drug Product 5
B. Essentially a Copy of a Commercially Available Drug Product 5
IV. PAPERWORK REDUCTION ACT 11
APPENDIX A. 12

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act
Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or the Agency) on this topic. It does not create any rights for any person and is not binding on FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed in the title page.

I. INTRODUCTION AND SCOPE

To qualify for exemptions under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a drug product must be compounded by a licensed pharmacist or physician who does not compound regularly or in inordinate amounts any drug products that are essentially copies of a commercially available drug product, among other conditions. This guidance sets forth FDA's policies regarding this provision of section 503A, including the terms *commercially available*, *essentially a copy of a commercially available drug product*, and *regularly or in inordinate amounts*.[2]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research, in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

[2] This guidance does not apply to drugs compounded for use in animals, to biological products subject to licensure in a biologics license application, or to repackaged drug products. For policies pertaining to mixing, diluting, and repackaging biological products, see FDA's guidance, *Mixing, Diluting, and Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.* For policies pertaining to repackaged drug products, see FDA's guidance, *Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities*.

All FDA guidances are available on the FDA guidance web page. FDA updates guidances regularly. To make sure you have the most recent version of a guidance, always consult the guidance web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

II. BACKGROUND

A. Section 503A of the FD&C Act

Section 503A, added to the FD&C Act by the Food and Drug Administration Modernization Act of 1997 and amended by the Drug Quality and Security Act in 2013, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to qualify for exemptions from the following three sections of the FD&C Act:[3]

- Section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP) requirements)
- Section 502(f)(1) (concerning the labeling of drugs with adequate directions for use)
- Section 505 (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs))

One of the conditions that must be met for a compounded drug product to qualify for the exemptions under section 503A of the FD&C Act is that it must be compounded by a licensed pharmacist or a licensed physician that "does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product."[4]

The statute further states that "the term 'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug."[5]

A complete list of the conditions that must be met for a compounded drug product to qualify for the exemptions in section 503A appears in the FDA guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*.

B. Compounding, Generally

Compounded drug products serve an important role for patients whose clinical needs cannot be met by an FDA-approved drug product, such as a patient who has an allergy and needs a medication to be made without a certain dye, an elderly patient who cannot swallow a pill and needs a medicine in a liquid form that is not otherwise available, or a child who needs a drug in a strength that is lower than that of the commercially available product. Drug products for identified individual patients can be compounded by licensed pharmacists in state-licensed

[3] In addition, under section 581(13) of the FD&C Act, the term "product," for purposes of pharmaceutical supply chain security requirements, does not include a drug compounded in compliance with section 503A.

[4] See section 503A(b)(1)(D).

[5] See section 503A(b)(2).

pharmacies and Federal facilities and by licensed physicians operating under section 503A of the FD&C Act. Drug products can also be compounded by outsourcing facilities under section 503B of the FD&C Act for identified individual patients pursuant to prescriptions or for distribution to health care practitioners without first receiving a prescription.[6] Both sections 503A and 503B restrict compounding drug products that are essentially a copy of a commercially available drug product (section 503A) or an approved drug product (section 503B).

C. Risks Associated with Compounded Drug Products

Although compounded drugs can serve an important need, they can also pose a higher risk to patients than FDA-approved drugs. Compounded drug products are not FDA-approved, which means they have not undergone FDA premarket review for safety, effectiveness, and quality. In addition, licensed pharmacists and licensed physicians who compound drug products in accordance with section 503A are not required to comply with CGMP requirements. Furthermore, FDA does not interact with the vast majority of licensed pharmacists and licensed physicians who compound drug products and seek to qualify for the exemptions under section 503A of the FD&C Act for the drug products that they compound because these compounders are not licensed by FDA and generally do not register their compounding facilities with FDA. Therefore, FDA is often not aware of potential problems with their compounded drug products or compounding practices unless it receives a complaint, such as a report of a serious adverse event or visible contamination.

FDA has investigated numerous serious adverse events associated with compounded drug products that were contaminated or otherwise compounded improperly, including the adverse events associated with the 2012 fungal meningitis outbreak in which contaminated injectable drug products resulted in more than 60 deaths and 750 cases of infection. FDA has also identified many pharmacies that compounded drug products under insanitary conditions such that the drug products may have been contaminated with filth or rendered injurious to health and that shipped the compounded drug products made under these conditions to patients and health care practitioners across the country, sometimes in large amounts.

D. Compounded Drugs That Are Essentially Copies of Commercially Available Drug Products

Section 503A provides exemptions from new drug approval, labeling with adequate directions for use, and CGMP requirements of the FD&C Act, so that drug products can be compounded as customized therapies for identified individual patients whose medical needs cannot be met by commercially available drug products. The restrictions on making drugs that are essentially copies ensure that pharmacists and physicians do not compound drug products under the exemptions for patients who could use a commercially available drug product. Such a practice would create significant public health risks because patients would be unnecessarily exposed to drug products that have not been shown to be safe and effective and that may have been prepared

[6] Section 503B of the FD&C Act describes the conditions that must be met for a human drug product compounded by an outsourcing facility to qualify for exemptions from sections 505, 502(f)(1), and 582 (concerning drug supply chain security requirements) of the FD&C Act. The conditions applicable to outsourcing facilities are discussed in separate guidances applicable to those facilities.

under substandard manufacturing conditions. FDA has investigated serious adverse events in patients who received contaminated compounded drugs when a comparable approved drug, made in a facility subject to CGMP requirements, was available.

In addition to these immediate public health risks, section 503A's limitations on producing a drug product that is essentially a copy of a commercially available drug product protects the integrity and effectiveness of the new drug and abbreviated new drug approval processes that Congress put in place to protect patients from unsafe, ineffective, or poor quality drugs. Furthermore, sponsors may be less likely to invest in and seek approval of innovative, life-saving medications if a compounder could, after a drug is approved, compound "substitutes" that may be less expensive because they have not had to demonstrate safety and effectiveness and are not produced in accordance with CGMP requirements or labeled with adequate directions for use.

Sponsors might also be less likely to seek approval of an ANDA for a generic drug if compounders were permitted to compound drugs that are essentially copies of commercially available drugs without going through the ANDA process. An ANDA must include data to demonstrate that the drug has the same active ingredient and is bioequivalent to an approved drug. FDA also conducts premarketing inspections of proposed manufacturing facilities.

The copies restriction also protects FDA's drug monograph process. FDA has an ongoing process for evaluating the safety and effectiveness of certain over-the-counter (OTC) medications, and if the Agency determines that an OTC drug meets certain conditions and is generally recognized as safe and effective, it will publish a final monograph specifying those conditions. Products that comply with a final monograph may be marketed, but manufacturers are required to meet CGMP standards. Restrictions in section 503A prevent compounders from producing drugs without having to comply with monograph standards, or CGMP requirements.

III. POLICY

As stated above, to qualify for the exemptions under section 503A of the FD&C Act, a drug must be compounded by a licensed pharmacist or a licensed physician that does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.[7] This means that a compounded drug product is not eligible for the exemptions in section 503A if it is (1) essentially a copy of a commercially available drug product, and (2) compounded regularly or in inordinate amounts. Accordingly, and as discussed below, when evaluating whether a drug product meets the condition in section 503A regarding essentially copies, FDA intends to determine whether a compounded drug product is *essentially a copy of a commercially available drug product:* if it is, FDA intends to determine whether the drug product was compounded regularly or in inordinate amounts.[8]

[7] See section 503A(b)(1)(D).

[8] FDA is considering the applicability of the policies described in this guidance to hospitals and health systems and intends to address these issues in separate guidance or rulemaking. FDA regards a health system as collection of hospitals that are owned and operated by the same entity and that share access to databases with drug order information for their patients. There is no definition of "health system" that applies to all sections of the FD&C Act.

FDA's policies with regard to the terms (1) *commercially available drug product*, (2) *essentially a copy of a commercially available drug product*, and (3) *regularly or in inordinate amounts*, are as follows:

A. Commercially Available Drug Product

For purposes of this guidance, a drug product is commercially available if it is a marketed drug product.

We do not consider a drug product to be commercially available if

- the drug product has been discontinued and is no longer marketed[9] or
- the drug product appears on the FDA drug shortage list in effect under section 506E of the FD&C Act.[10] A drug "appears on the drug shortage list in effect under section 506E" if the drug is in "currently in shortage" status (and not in "resolved" status) in FDA's drug shortage database.

Commercially available drugs are available on the market, and they are generally subject to FD&C Act requirements relating to approval, labeling, and CGMP requirements, and the copies restriction applies to all such drugs because section 503A is not intended to provide a means for compounders to produce compounded drugs exempt from the Act's requirements that are essentially copies of commercially available drug products.

B. Essentially a Copy of a Commercially Available Drug Product

1. What is Essentially a Copy?

FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if:

- the compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product;
- the API(s) have the same, similar, or an easily substitutable dosage strength; and

---

However, this is the definition of a "health system" used in section 506F of the Act concerning hospital repackaging of drugs in shortage.

[9] FDA maintains a list of approved drug products that sponsors have indicated are not marketed in the discontinued section of the list of Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). See http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Specifically, the list includes approved drug products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing and we have not determined were withdrawn for safety or effectiveness reasons, or have had their approvals withdrawn for reasons other than safety or effectiveness subsequent to being discontinued from marketing.

[10] See http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

- the commercially available drug product can be used by the same route of administration as prescribed for the compounded drug,

unless, as provided by section 503A(b)(2), a prescriber determines that there is a change, made for an identified individual patient, which produces, for that patient, a significant difference from the commercially available drug product.

The limitations in section 503A(b)(1)(D) apply to the compounding of drug products that are *essentially* copies of a commercially available drug product – not only to drugs that are exact copies or even to drugs that are nearly identical. This is to ensure that compounders do not evade the limits in this section by making relatively small changes to a compounded drug product and then offering the drug to the general public without regard to whether a prescribing practitioner has determined that the change produces for the patient a significant difference. For example, Congress contemplated that a compounded drug may be essentially a copy of a commercially available drug if "minor changes in strength (such as from .08% to .09%) are made that are not known to be significant . . ." for the patient for whom the drug was prescribed.[11]

a. Same API

With regard to the characteristics listed above, an API is the substance in a drug product that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body.[12] When a compounded drug product offers the same API as a commercially available drug product, in the same, similar, or easily substitutable dosage strength and for use through the same route of administration, we generally intend to consider such a drug product *essentially a copy*, unless a prescriber determines that there is a change, made for an identified individual patient, that will produce a significant difference for that patient.

We recognize that, for some patients, a drug product that has the same API, strength, and route of administration may include a change that produces a significant difference for a particular patient. For example, a drug product compounded without a particular inactive ingredient may produce a significant difference for a patient who has an allergy to the inactive ingredient in the commercially available drug product. However, for other patients, this change may produce no difference at all. Congress did not intend for compounders to use, for example, the fact that some patients may have allergies as a basis to compound a drug without the inactive ingredient for other patients who do not have the allergy under the exemptions in section 503A (i.e., without meeting requirements for premarket approval, labeling with adequate directions for use, or

[11] U.S. House. Food and Drug Administration Modernization Act of 1997, *Conference Report* (to Accompany S. 830). (105 H. Rpt. 399).

[12] Section 503A refers to bulk drug substances. A *bulk drug substance* is defined as any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. It does not include intermediates used in the synthesis of the substance. This definition is the same as the definition of active pharmaceutical ingredient. See 21 CFR 207.1, 207.3.

CGMP requirements).[13] In the context of compounding and consistent with the statute, we generally intend to consider such a drug essentially a copy unless a prescriber determines that there is a change that will produce a significant difference for the patient for whom it is prescribed.

b. Same, Similar or Easily Substitutable Strength

FDA generally intends to consider two drugs to have a similar dosage strength if the dosage strength of the compounded drug is within 10% of the dosage strength of the commercially available drug product.

With regard to the concept of easily substitutable strength, in some cases, the same or similar dosage strength can be achieved by administration of fractional or multiple doses of a drug product. For example, if FDA-approved Drug X tablets have a dosage strength of 25 mg and a patient needs 50 mg of Drug X, FDA would generally consider a compounded Drug X 50 mg tablet to have an easily substitutable strength because the patient could take two Drug X 25 mg tablets to achieve the required dose.[14]

c. Same Route of Administration

Route of administration is a way of administering a drug to a site in a patient (e.g., topical, intravenous, oral).[15] In general, FDA does not intend to consider a compounded drug product with the same API and similar or easily substitutable strength to be essentially a copy of a commercially available drug product if the compounded drug product and the commercially available drug product have different routes of administration (e.g., if the commercially available drug product is oral and the compounded drug product is topical). However, if the compounded drug product has the same API and similar or easily substitutable strength as the commercially available drug product and the commercially available drug product can be used (regardless of how it is labeled) by the route of administration prescribed for the compounded drug, FDA generally intends to consider the compounded drug to be essentially a copy of the commercially available drug. In this case, the compounded drug product generally would not produce a significant difference for an identified individual patient relative to the commercially available drug product.

For example, if the commercially available drug is an injectable drug sold in a vial that is labeled for intra-muscular use, but the drug also can be drawn from the vial by a smaller needle for subcutaneous administration, a compounded drug product with the same API and similar or

[13] *See* note 11.

[14] If a commercially available tablet must be split to achieve the prescribed dosage strength, and such tablet is not suitable for splitting, FDA would not consider the compounded drug made to the prescribed dosage strength to have an easily substitutable strength. For example, some tablets may be too small or crumble too easily when split, making splitting an inappropriate option. Information regarding tablet splitting may be printed in the "HOW SUPPLIED" section of the professional label insert and in the patient package insert of an approved drug product.

[15] See http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071667.htm.

easily substitutable strength prescribed for sub-cutaneous administration would generally be considered to be essentially a copy, unless the prescriber documents on the prescription that the compounded drug product produces a significant difference for the identified individual patient.

d. Same Characteristics as Two or More Commercially Available Drug Products

FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug product if the compounded drug product contains the same APIs as two or more commercially available drug products in the same, similar, or easily substitutable strength and if the commercially available drug products can be used (regardless of how they are labeled) by the same route of administration prescribed for the compounded drug, unless there is documentation as described in section III.B.2. Such drug products present the same kinds of concerns as drug products that have a single API and in some respects may be more dangerous because of the potential for unintended drug interactions or formulation issues. For example, if drug X and drug Y are commercially available oral drug products, FDA generally intends to consider a compounded oral drug product that combines drug X and drug Y in strengths that are within 10% of the strengths of the respective commercially available products to be essentially a copy of the commercially available drug product, unless a prescriber determination of a significant difference has been documented.

2. Statement of Significant Difference

Pursuant to section 503A(b)(2) of the FD&C Act, a compounded drug product is not essentially a copy of a commercially available drug product if a change is made for an identified individual patient, and the prescribing practitioner has determined that the change will produce a significant difference for that patient. If a compounder intends to rely on such a determination to establish that a compounded drug is not essentially a copy of a commercially available drug product, the compounder should ensure that the determination is documented on the prescription.

FDA does not believe that a particular format is needed to document the determination, provided that the prescription makes clear that the prescriber identified the relevant change and the significant difference that the change will produce for the patient. For example, the following would be sufficient:

- "No Dye X, patient allergy" (if the comparable drug contains the dye)
- "Liquid form, patient can't swallow tablet" (if the comparable drug is a tablet)
- "6 mg, patient needs higher dose" (if the comparable drug is only available in 5 mg dose)

However, if a prescription identifies only a patient name and drug product formulation, this would not be sufficient to establish that the prescriber made the determination described by section 503A(b)(2). Note also that the significant benefit that the prescriber identifies must be produced by the change the compounder will make to a commercially available drug product (i.e., a change in drug product formulation). Other factors, such as a lower price, are not

sufficient to establish that the compounded drug product is not essentially a copy of the commercially available drug product.[16]

If a prescription does not make clear that the prescriber made the determination required by section 503A(b)(2), or a compounded drug is substituted for the commercially available drug product, the compounder can contact the prescriber and if the prescriber confirms it, make a notation on the prescription that the compounded drug product contains a change that makes a significant difference for the patient. The notations should be as specific as those described above, and the date of the conversation with the prescriber should be included on the prescription.[17]

It is not possible to offer exhaustive guidance about when a difference will be "significant" to an identified individual patient. At this time, FDA generally does not intend to question prescriber determinations that are documented in a prescription or notation. However, we do intend to consider whether a prescription or notation relied upon by a compounder to establish that a drug is not essentially a copy documents that the determination was made.

If the compounder produces drugs in anticipation of receiving valid prescriptions for identified individual patients, and the compounder obtains the statement of significant difference from the prescriber when it receives the prescription for the compounded drug, prior to distribution, FDA does not intend to consider the compounded drug that is then distributed to be essentially a copy.

3. Documentation of Shortage

If the drug was compounded because the approved drug product was not commercially available because it was on the FDA drug shortage list, the prescriber or compounder should include a notation on the prescription that it was on the drug shortage list and the date the list was checked.[18]

4. Regularly or in Inordinate Amounts

A drug product is not eligible for the exemptions in section 503A if it is prepared by a pharmacist or physician who compounds "regularly or in inordinate amounts (as defined by the Secretary)" any drug products that are essentially copies of a commercially available drug

[16] Congress noted that "where it is readily apparent, based on the circumstances, that the 'significant difference' is a mere pretext to allow compounding of products that are essentially copies of commercially available products, such compounding would be considered copying of commercially available products and would not qualify for the compounding exemptions if it is done regularly or in inordinate amounts. Such circumstances may include, for example, instances in which minor changes in strength (such as from .08% to .09%) are made that are not known to be significant or instances in which the prescribing physician is receiving financial remuneration or other financial incentives to write prescriptions for compounded products." *See* the U.S. House. Food and Drug Administration Modernization Act of 1997, *Conference Report* (to Accompany S. 830). (105 H. Rpt. 399).

[17] See section IV of this guidance.

[18] See section IV of this guidance.

product.[19] FDA interprets this to mean that, in order to be compounded in accordance with section 503A, a drug product that is essentially a copy of a commercially available drug product cannot be compounded regularly – i.e., it cannot be compounded at regular times or intervals, usually, or very often. Nor can the amounts compounded be inordinate, in light of the purpose of section 503A.

Section 503A is intended to protect patients from the public health risks of providing compounded drugs to patients whose medical needs could be met by commercially available drug products and to protect the integrity and efficiency of the drug approval process. Under the statutory scheme, only very rarely should a compounded drug product that is essentially a copy of a commercially available drug product be offered to a patient. We conclude, therefore, that a drug product that is essentially a copy of a commercially available drug product is compounded regularly or in inordinate amounts if it is compounded more frequently than needed to address unanticipated, emergency circumstances, or in more than the small quantities needed to address unanticipated, emergency circumstances.

It is important to note that the regularly or in inordinate amounts provision is not implicated if the compounded drug is not essentially a copy of a commercially available drug product. For example, a compounded drug product that has the same API, dosage strength, and route of administration as a drug product on FDA's shortage list would not be considered essentially a copy of a commercially available drug because a drug product is not considered *commercially available* if it is on FDA's drug shortage list. In addition, a compounded drug product is not essentially a copy of a commercially available drug product if a prescriber has determined that the compounded drug has a change that produces a significant difference for a patient.
Once it has been determined that a compounded drug is essentially a copy of a commercially available drug product as described above, the following are examples of factors that may be the basis for concluding that it has been compounded regularly or in inordinate amounts:

- The compounded drug product amounts to more than a small number of prescriptions or a small percentage of the compounded drug products that a compounder prepares.
- The compounder routinely substitutes compounded drugs that are essentially copies of commercially available drugs upon receiving prescriptions for patients.
- The compounder offers pre-printed prescription pads that a prescriber can use to write a prescription for the drug product that is essentially a copy without making a determination that there is a change that will produce a significant difference for a patient.
- The compounded drug product is not compounded on an as-needed basis, but on a routine or pre-set schedule.

The foregoing list is not intended to be exhaustive. Other factors may be appropriate for consideration in a particular case.

To focus enforcement on the most significant cases, as a matter of policy, at this time FDA does not intend to take action against a compounder for compounding a drug product that is

[19] See section 503A(b)(1)(D).

essentially a copy of a commercially available drug product regularly or in inordinate amounts if the compounder fills four or fewer prescriptions for the relevant compounded drug product in a calendar month.[20] As noted above, a compounded drug product is not essentially a copy of a commercially available drug product if a prescriber has determined that the compounded drug has a change that produces a significant difference for a patient; thus, a prescription that documents such a prescriber determination would not be counted towards the four prescriptions.

Compounders may produce a limited amount of drugs in anticipation of receiving valid prescriptions for identified individual patients. See section 503A(a)(2). FDA generally intends to consider whether such drugs are essentially a copy at the time the drug is distributed rather than the time it is produced.

5. Recordkeeping

A licensed pharmacist or physician seeking to compound a drug product under section 503A should maintain records to demonstrate compliance with section 503A(b)(1)(D). For example, records should be kept of notations on prescriptions for identified individual patients that a prescriber has determined that the compounded drug has a change that produces a significant difference for the identified patient.

Compounders under section 503A should also maintain records of the frequency in which they have compounded drug products that are essentially copies of commercially available drug products and the number of prescriptions that they have filled for compounded drug products that are essentially copies of commercially available drug products to document that such compounding has not been done regularly or in inordinate amounts.[21]

FDA recommends that compounders maintain the records described above for a period of at least three years.

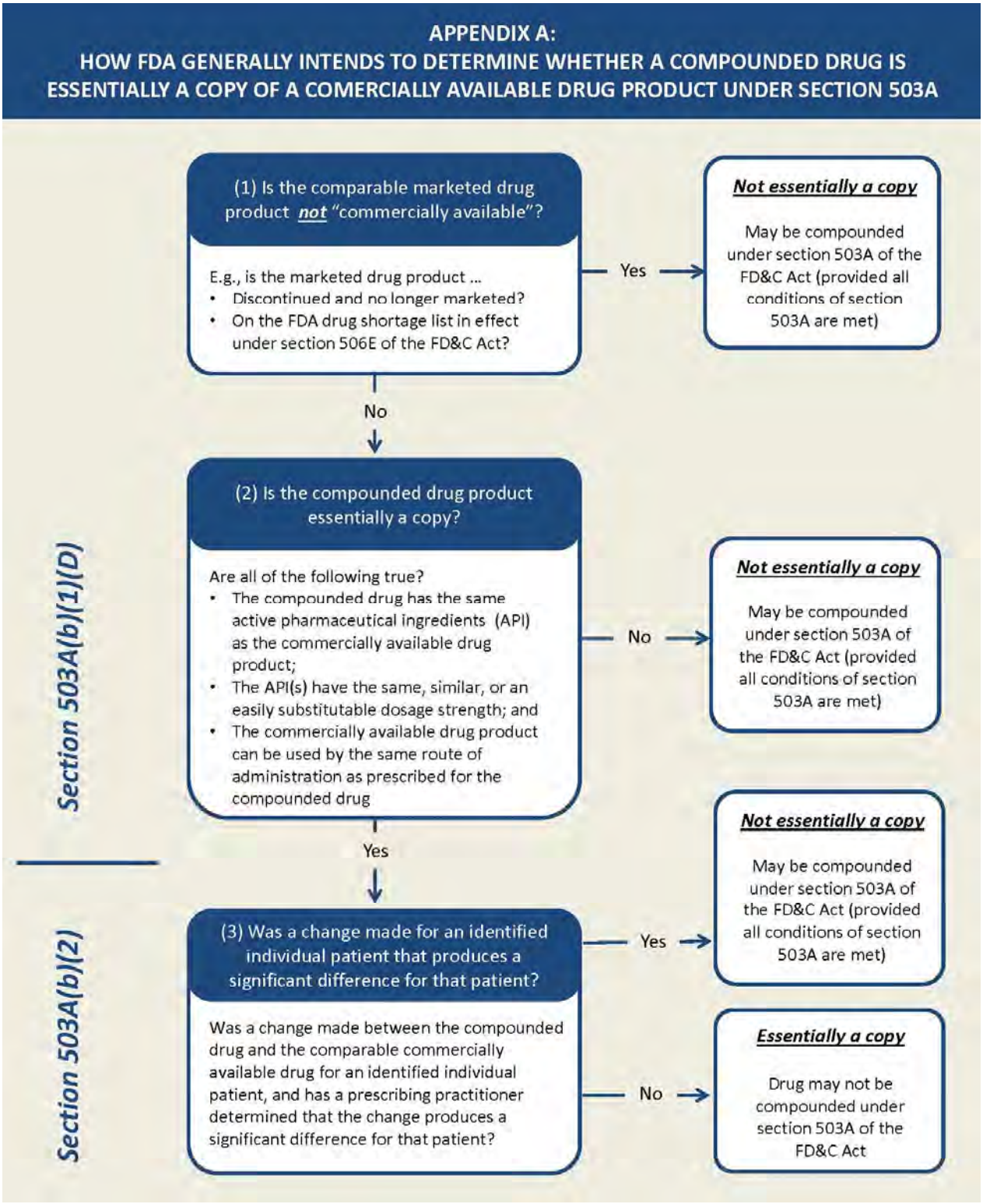
IV. PAPERWORK REDUCTION ACT

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). See footnotes 17, 18, and 21. These provisions require review and are not in effect until they display a currently valid OMB control number. The information collection provisions in this guidance have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. FDA will publish a notice in the *Federal Register* announcing OMB's decision regarding the information collection provisions in this guidance.

[20] For purposes of this policy, FDA intends to consider each refill of a prescription as an additional prescription.

[21] See section IV of this guidance.

APPENDIX A.


APPENDIX A:
HOW FDA GENERALLY INTENDS TO DETERMINE WHETHER A COMPOUNDED DRUG IS ESSENTIALLY A COPY OF A COMERCIALLY AVAILABLE DRUG PRODUCT UNDER SECTION 503A
(1) Is the comparable marketed drug product not "commercially available"?
E.g., is the marketed drug product ...
• Discontinued and no longer marketed?
• On the FDA drug shortage list in effect under section 506E of the FD&C Act?
Yes
Not essentially a copy
May be compounded under section 503A of the FD&C Act (provided all conditions of section 503A are met)
No
Section 503A(b)(1)(D)
(2) Is the compounded drug product essentially a copy?
Are all of the following true?
• The compounded drug has the same active pharmaceutical ingredients (API) as the commercially available drug product;
• The API(s) have the same, similar, or an easily substitutable dosage strength; and
• The commercially available drug product can be used by the same route of administration as prescribed for the compounded drug
No
Not essentially a copy
May be compounded under section 503A of the FD&C Act (provided all conditions of section 503A are met)
Yes
Section 503A(b)(2)
(3) Was a change made for an identified individual patient that produces a significant difference for that patient?
Was a change made between the compounded drug and the comparable commercially available drug for an identified individual patient, and has a prescribing practitioner determined that the change produces a significant difference for that patient?
Yes
Not essentially a copy
May be compounded under section 503A of the FD&C Act (provided all conditions of section 503A are met)
No
Essentially a copy
Drug may not be compounded under section 503A of the FD&C Act

5M

FILED
JUL 2 1 2026
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JAYZLE JOY BOYD JUSTICE, RPH, Certificate of Registration No. 19506,** **Respondent.**	**CASE NO. 26-137-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this Respondent because at the time of the events alleged herein, Respondent Jayzle Joy Boyd Justice, RPh, Certificate of Registration No. 19506, was a pharmacist registered with the Board.

FACTUAL ALLEGATIONS

2. On or about June 10, 2024, in case no. 24-248-RPH-S Board staff issued a citation to Respondent and imposed a $500 fine for failing to complete the thirty (30) hours of continuing education required by NAC 639.330 for the biennial registration period starting November 1, 2021, and ending on October 31, 2023.

3. Respondent failed to complete the thirty (30) hours of continuing education required by NAC 639.330 for the biennial registration period starting November 1, 2023, and ending on October 31, 2025.

4. Respondent attempted to submit the Nevada law continued education credit she claimed in the 2023-25 CE audit for credit.

APPLICABLE LAW

5. The Board shall not renew the certificate of any registered pharmacist until the applicant submits proof to the Board of receipt of 30 continuing education units within the biennium immediately preceding the current renewal period. NRS 639.2174; NAC 639.330(1).

6. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(i) and is grounds for suspension or revocation of any registration issued by the Board. NRS 639.210(4).

7. The Board may suspend or revoke a registration if the holder has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

COUNT ONE

Violation of State Law/Unprofessional Conduct

8. Respondent engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and violated NRS 639.2174 and NAC 639.330(1) when she failed to complete the thirty (30) hours of continuing education required by NAC 639.330 for the biennial registration period, and is subject to discipline pursuant to NRS 639.210(4) and/or (12).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 21st day of JULY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JAYZLE JOY BOYD JUSTICE, RPH,** **Certificate of Registration No. 19506,** **Respondent.**	**Case No. 26-137-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 21st day of JULY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JAYZLE JOY BOYD JUSTICE, RPH,** **Certificate of Registration No. 19506,** **Respondent.**	**Case No. 26-137-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

JAYZLE JOY BOYD JUSTICE, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 31st day of July 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Jayzle Joy Boyd Justice
[redacted]
Las Vegas, NV [redacted]

Jayzle Joy Boyd Justice
c/o CVS Pharmacy
4100 Blue Diamond Rd.
Las Vegas, NV 89139

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
AUG 20 2026
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JAYZLE JOY BOYD JUSTICE, RPH, Certificate of Registration No. 19506,** **Respondent.**	**Case No. 26-137-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

See attached.

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

See attached.

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

JAYZLE JOY BOYD JUSTICE, RPH

RESPONDENT'S ANSWER TO NOTICE OF INTENDED ACTION AND ACCUSATION

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,
Petitioner,

v.

JAYZLE JOY BOYD JUSTICE, RPh,
Respondent.

Case No. 26-137-RPH-S

RESPONDENT'S ANSWER TO NOTICE OF INTENDED ACTION AND ACCUSATION

Respondent, **Jayzle Joy Boyd Justice, RPh**, respectfully submits this Answer to the Notice of Intended Action and Accusation and states as follows:

I. GENERAL RESPONSE

Respondent acknowledges the importance of complying with all continuing education requirements applicable to her Nevada pharmacist registration.

Respondent acknowledges that the Nevada Law continuing education requirement applicable to the **November 1, 2023, through October 31, 2025 biennial renewal period** was not completed within the required timeframe.

Respondent respectfully denies, however, that she intentionally engaged in deceptive conduct, falsified any continuing education documentation, or intentionally attempted to circumvent the continuing education requirements of the Nevada State Board of Pharmacy.

Respondent respectfully submits that the circumstances involve a limited continuing education timing and compliance deficiency concerning the required Nevada Law CE, rather than falsification or intentional dishonesty.

As confirmed by Darlene Nases, Board Coordinator and Custodian of Records, the Board's records reflect that Respondent completed the general continuing education requirements for the 2023–2025 biennial period and that the identified deficiency was the failure to complete a Nevada Law CE within the required timeframe.

II. RESPONSE TO FACTUAL ALLEGATIONS

Respondent admits the allegations concerning the jurisdiction of the Nevada State Board of Pharmacy and Respondent's status as a licensed or registered pharmacist, to the extent accurately stated.

Respondent admits that she was previously audited regarding the **November 1, 2021, through October 31, 2023 biennial renewal period**.

The Board determined that Respondent's September 12, 2021 Nevada Law CE did not fall within the applicable audit period and therefore could not be accepted for that biennium. Respondent was subsequently assessed a $500 fine.

Respondent subsequently completed a **2023 Nevada Law CE on April 29, 2024**, which the Board's records reflect satisfied the Nevada Law CE requirement for the prior biennial renewal period.

Respondent acknowledges that the present matter concerns the **November 1, 2023, through October 31, 2025 biennial renewal period.**

Respondent acknowledges that the April 29, 2024 Nevada Law CE was applied to satisfy the requirement associated with the prior biennial period and could not also be applied to satisfy the Nevada Law CE requirement for the 2023–2025 biennium. The Board's records expressly reflect that the April 29, 2024 course was already used to meet the prior renewal requirement.

Respondent respectfully submits, however, that the Board's own records confirm that Respondent **completed the general continuing education requirements** for the 2023–2025 biennial period. The deficiency identified by the Board was limited to the Nevada Law CE requirement.

Respondent admits that she submitted a Nevada Law continuing education certificate during the audit process.

Respondent denies that she submitted any certificate with the intent to deceive the Board or intentionally misrepresent her continuing education compliance.

The Nevada Law CE certificate submitted by Respondent was authentic. Respondent did not create, alter, fabricate, or falsify the certificate.

Respondent acknowledges that the April 29, 2024 Nevada Law CE had already been used to satisfy the prior biennial requirement and therefore could not also be applied to the subsequent 2023–2025 biennium.

Respondent accepts responsibility for failing to ensure that a separate Nevada Law CE was completed within the required timeframe for the subsequent biennium.

III. SUBSEQUENT COMPLETION OF NEVADA LAW CE

After the expiration of the October 31, 2025 deadline, Respondent completed a separate **2025 Nevada Law CE on February 6, 2026.**

The Board's records, as confirmed by Darlene Nases, Board Coordinator and Custodian of Records, reflect that the February 6, 2026 Nevada Law CE can be applied toward the current audit biennial renewal, although the Board considers Respondent noncompliant with the applicable deadline because the course was completed after October 31, 2025.

Respondent respectfully submits that this subsequent completion demonstrates corrective action and a continuing effort to satisfy the Nevada Law CE requirement.

Respondent does not contend that the February 6, 2026 completion occurred before the October 31, 2025 deadline. Rather, Respondent requests that the Board consider the subsequent completion as evidence of corrective action and mitigation in determining the appropriate disposition of this matter.

IV. RESPONSE TO COUNT ONE

Respondent acknowledges her responsibility to complete all required continuing education within the applicable biennial period.

Respondent respectfully denies that the circumstances establish intentional deception, falsification, or intentional misconduct.

The evidence establishes that:

1. Respondent completed the general CE requirements for the 2023–2025 biennium;
2. The deficiency identified by the Board was limited to the Nevada Law CE requirement within the applicable timeframe;
3. Respondent submitted an authentic Nevada Law CE certificate;
4. Respondent did not create, alter, fabricate, or falsify any CE documentation;
5. The April 29, 2024 Nevada Law CE was applied to the prior biennial requirement and could not also be used for the 2023–2025 biennium; and
6. Respondent subsequently completed a separate 2025 Nevada Law CE on February 6, 2026, which the Board's records recognize, although it was completed after the deadline for the biennium at issue.

Respondent respectfully submits that these facts should be considered in determining whether the alleged conduct warrants the discipline sought and, if so, the appropriate level of corrective action.

V. GOOD-FAITH CONDUCT AND MITIGATING CIRCUMSTANCES

Respondent respectfully asks the Board to consider the following mitigating circumstances:

1. **The CE deficiency was limited in scope.** The Board's records reflect that Respondent completed the general continuing education requirements for the 2023–2025 biennium.
2. **The identified deficiency concerned the timing of one Nevada Law CE requirement.** The Board determined that a qualifying Nevada Law CE was not completed within the required biennial timeframe.
3. **The certificate submitted was authentic.** Respondent did not fabricate, alter, or falsify continuing education documentation.
4. **Respondent subsequently completed the Nevada Law CE.** The Board's records show completion of a 2025 Nevada Law CE on February 6, 2026.
5. **Respondent accepts responsibility for the timing deficiency.** Respondent understands that each biennium requires compliance within the applicable period.
6. **Respondent has taken corrective steps.** Respondent has reviewed the continuing education requirements and intends to maintain a more structured system for tracking CE completion dates and biennial applicability.
7. **Respondent is willing to comply with additional corrective requirements.** Respondent is willing to complete any additional Board-approved education or other reasonable corrective measure deemed appropriate.

VI. CORRECTIVE ACTION

Respondent has taken or is taking the following corrective actions:

1. Completed a separate 2025 Nevada Law CE on February 6, 2026;
2. Reviewed the Nevada continuing education requirements applicable to each biennial renewal period;
3. Reviewed her CE records to ensure that courses are assigned to the appropriate biennium;
4. Established a process to track the completion date and expiration of each required CE activity;
5. Will retain CE certificates and supporting documentation for each applicable biennial period; and
6. Will verify compliance with all CE requirements before future renewal and audit deadlines.

VII. REQUEST FOR RELIEF

Respondent respectfully requests that the Board consider the complete factual record, including the Board's own confirmation that:

- Respondent completed the general CE requirements for the 2023–2025 biennium;
- the deficiency was limited to the Nevada Law CE requirement within the applicable timeframe; and
- Respondent subsequently completed a separate Nevada Law CE on February 6, 2026.

Respondent respectfully requests that the Board consider the limited nature of the deficiency, the authenticity of the documentation submitted, the absence of falsification or alteration, Respondent's subsequent completion of the required subject matter, and Respondent's corrective actions.

If the Board determines that discipline is appropriate, Respondent respectfully requests the **least restrictive corrective action appropriate under the circumstances.**

Respondent further respectfully requests that the Board consider a corrective or remedial resolution, rather than suspension or revocation of Respondent's pharmacist registration.

Respondent is willing to comply with reasonable corrective conditions, including additional Board-approved continuing education, if deemed appropriate.

Respectfully submitted,

JAYZLE JOY BOYD JUSTICE, RPh
Nevada Pharmacist Registration No. 19506

Date: August 20, 2026

Signature: Jayzle Joy Justice

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JAYZLE JOY BOYD JUSTICE, RPH,** **Certificate of Registration No. 19506,** **Respondent.**	**CASE NO. 26-137-RPH-S** **STIPULATION AND ORDER**

David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Jayzle Joy Boyd Justice, RPh, Certificate of Registration No. 19506, **HEREBY STIPULATE AND AGREE THAT**:

1. On or about July 31, 2026, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing. R

2. On or about August 20, 2026, Respondent filed an Answer and Notice of Defense to the Accusation.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with

the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. On or about June 10, 2024, in case no. 24-248-RPH-S Board staff issued a citation to Respondent and imposed a $500 fine for failing to complete the thirty (30) hours of continuing education required by NAC 639.330 for the biennial registration period starting November 1, 2021, and ending on October 31, 2023;

B. Respondent failed to complete the thirty (30) hours of continuing education required by NAC 639.330 for the biennial registration period starting November 1, 2023, and ending on October 31, 2025, and attempted to submit the Nevada law continued education credit she claimed in the 2023-25 CE audit for credit; and

C. Respondent engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and violated NRS 639.2174 and NAC 639.330(1) when she failed to complete the thirty (30) hours of continuing education required by NAC 639.330 for the biennial registration period, and is subject to discipline pursuant to NRS 639.210(4) and/or (12).

7. Those violations are plead with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

8. On or about February 6, 2026, Respondent completed the Nevada law continuing education required for the 2023-25 biennial registration period.

9. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Jayzle Joy Boyd Justice, RPh, Certificate of Registration No. 19506, stipulate to the following penalties:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of One Thousand Dollars ($1,000.00) for the violations, by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2026; and

B. Pursuant to NRS 622.400, Respondent shall pay Five Hundred Dollars ($500.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2026.

10. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 639.

11. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 14, 2026. Respondent will appear in person or through counsel at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

12. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

13. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the

merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

14. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 23 day of August 2026

Jayzle Joy Justice

JAYZLE JOY BOYD JUSTICE, RPH
Certificate of Registration No. 19506

Signed this ___ day of _____ 2026

BRETT KANDT
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Jayzle Joy Boyd Justice, RPh, Certificate of Registration No. 19506, in Case No. 26-137-RPH-S, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of October 2026.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

5N

FILED
JUL 2 1 2026
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ABOLFAZL HOSSEINPOUR, RPH, Certificate of Registration No. 13587,** **Respondent.**	**CASE NO. 26-139-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this Respondent because at the time of the events alleged herein, Respondent Abolfazl Hosseinpour, RPh, Certificate of Registration No. 13587, was a pharmacist registered with the Board.

FACTUAL ALLEGATIONS

2. On or about May 22, 2024, in case no. 24-191-RPH-S Board staff issued a citation to Respondent and imposed a $500 fine for failing to complete the thirty (30) hours of continuing education required by NAC 639.330 for the biennial registration period starting November 1, 2021, and ending on October 31, 2023.

3. Respondent failed to complete the thirty (30) hours of continuing education required by NAC 639.330 for the biennial registration period starting November 1, 2023, and ending on October 31, 2025.

APPLICABLE LAW

4. The Board shall not renew the certificate of any registered pharmacist until the applicant submits proof to the Board of receipt of 30 continuing education units within the biennium immediately preceding the current renewal period. NRS 639.2174; NAC 639.330(1).

5. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(i) and is grounds for suspension or revocation of any registration issued by the Board. NRS 639.210(4).

6. The Board may suspend or revoke a registration if the holder has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

COUNT ONE

Violation of State Law/Unprofessional Conduct

7. Respondent engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and violated NRS 639.2174 and NAC 639.330(1) when he failed to complete the thirty (30) hours of continuing education required by NAC 639.330 for the biennial registration period, and is subject to discipline pursuant to NRS 639.210(4) and/or (12).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 21st day of JULY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ABOLFAZL HOSSEINPOUR, RPH,** **Certificate of Registration No. 13587,** **Respondent.**	**Case No. 26-139-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Brett Kandt at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 21st day of JULY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ABOLFAZL HOSSEINPOUR, RPH,** **Certificate of Registration No. 13587,** **Respondent.**	**Case No. 26-139-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

ABOLFAZL HOSSEINPOUR, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 31st day of July 2026, I served a true and correct copy of the foregoing document by Standard U.S. mail to the following:

Abolfazl Hosseinpour, RPh
[redacted]
Las Vegas, NV [redacted]

And via courtesy email to: [redacted]@yahoo.com

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

50

FILED
AUG 28 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **VALESCENT PHARMACEUTICALS, INC., License No. PH04636,** **REVIVE RX, License No. PH04215, and** **STRIVE PHARMACY, License No. PH04562,** **Respondents.**	**Case No. 24-482-PH-A-S** **24-482-PH-B-S** **24-482-PH-C-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter and these respondents because, at the time of the events alleged herein, Respondent Valescent Pharmaceuticals, Inc. ("VPI") held a license issued by the Board to operate a pharmacy, License No. PH04636, Respondent Revive Rx ("Revive") held a license issued by the Board to operate a pharmacy, License No. PH04215, and Respondent Strive Pharmacy ("Strive") held a license issued by the Board to operate a pharmacy, License No. PH04562.

\\\

\\\

\\\

FACTUAL ALLEGATIONS

2. Since October 17, 2024, VPI, an out-of-state compounding pharmacy located at 7265 S. Revere Parkway, Suite 902, in Centennial, Colorado, has held a pharmacy license in Nevada issued by the Board.

3. Since April 6, 2020, Revive, an out-of-state compounding pharmacy located at 3831 Golf Drive #A, in Houston, Texas, has held a pharmacy license in Nevada issued by the Board.

4. Since February 8, 2024, Strive, an out-of-state compounding pharmacy located at 1275 E. Baseline Road #104, in Gilbert, Arizona, has held a pharmacy license in Nevada issued by the Board.

5. Since on or about March 2022, Magnus Medical Health and Wellness ("Magnus") was a clinic located 8540 S. Eastern Avenue, Suite 160, in Las Vegas, Nevada. On or about September 2024, Magnus was renamed Young4Life.

6. During the timeframe of its operation, Magnus and Young4Life employed at least eight practitioners who transmitted prescriptions for patients to Revive Rx, VPI, and Strive. Two of the practitioners, Paul Branch, MD ("Branch") and Juanita Golden-Allen, APRN ("Golden-Allen) were not licensed by the Board to prescribe dangerous drugs or controlled substances in Nevada.

7. A Board investigation found that Revive Rx dispensed a total of 700 prescriptions sent using Branch's prescribing credentials for controlled substances and dangerous drugs to Nevada patients of Magnus and Young4Life between December 2024 and February 2025. At that time, Branch was not registered by the Board to prescribe drugs in Nevada.

8. A Board investigation found that in May 2024, Revive Rx dispensed one hundred twenty-eight (128) controlled substance prescriptions submitted using Golden-Allen's credentials for ninety-nine (99) unique Nevada patients. At that time, Golden-Allen was not registered by the Board to prescribe controlled substances in Nevada.

9. A Board investigation found that, during the relevant timeframe, in total, Revive dispensed one thousand one hundred and four (1,104) controlled substance prescriptions from Magnus/Young4Life prescribers for five hundred and seventeen (517) unique patients to just sixteen (16) addresses in Las Vegas and Henderson. At least one of the addresses is Magnus/Young4Life's business address, and 15 addresses are residential addresses.

10. A Board investigation found that, during the relevant timeframe, forty-nine (49) controlled substance prescriptions for eight (8) different patients were sent to Magnus/Young4Life's business address and fifteen (15) controlled substance prescriptions for five (5) unique patients were sent to the same residential address. Strive's internal investigation confirmed that multiple prescriptions for unique Magnus/Young4Life patients were sent to the same address.

11. Furthermore, a Board investigation found that between February 2024 and November 2024, some electronic prescriptions Strive received were not compliant with Electronic Prescribing of Controlled Substances standards. Following discovery of the compliance issues, Strive confirmed the findings through an internal investigation and took action to implement stronger two-factor authentication procedures.

12. Because of these compliance issues, from February 2024 and November 2024, at least three prescribers for Magnus/Young4Life did not have two-factor authentication enabled and were not EPCS compliant.

13. A Board investigation found that between March 2025 and May 2025, VPI filled seven prescriptions for seven different Nevada patients from Branch. Branch did not hold a license issued by the Board to prescribe in Nevada.

14. Between March 2022 and March 2024, VPI filled one thousand eight hundred forty-six (1,845) controlled substance prescriptions for seven hundred fourteen (713) unique Nevada patients from Miller-Wilson. According to the PMP report, fifty-two (52) controlled substance prescriptions were listed as "compounded drug product" and did not indicate the active ingredient of the compounded controlled substance.

PRIOR DISCIPLINE

15. On December 3, 2025, the Board disciplined Respondent Revive Rx for dispensing non-FDA approved drugs. The Board placed Respondent Revive Rx on one-year probation beginning on December 3, 2025, and ordered it to pay a $5,000 fine and $4,000 in fees and costs. Additionally, the Board ordered every pharmacist and pharmaceutical technician who engaged in the practice of sterile compounding to complete training related to sterile compounding. The Board also ordered Revive Rx to undergo quarterly inspections by the Board, one inspection by the National Associations of Boards of Pharmacy, and to establish compounding policies and procedures in conformance with Nevada and federal law.

APPLICABLE LAW

16. Pursuant to NRS 639.100(1), it is unlawful for any person to possess, store, administer and/or dispense dangerous drugs without having secured the appropriate license and/or certificate of registration from the Board.

17. Only those individuals or practitioners permitted to do so pursuant to NRS 453.375 may possess, store, or administer controlled substances. Practitioners include physicians who hold a license to practice in their state and who are also registered by the Board to prescribe

controlled substances; advanced practice registered nurses who hold a certificate from the Board authorizing them to prescribe controlled substances; and physician assistants who hold a license from the Nevada State Board of Medical Examiners and are authorized by the Board to prescribe controlled substances under the supervision of physician. NRS 453.126.

18. Pursuant to NRS 639.235(1), no person other than a practitioner holding a license to practice his or her profession in Nevada may prescribe or write a prescription, except that a prescription written by a person who is not licensed to practice in Nevada, but is authorized by the laws of another state to prescribe. If a prescription for a Schedule III controlled substance that is prescribed by a person who is not licensed to practice in Nevada, but is authorized by the laws of another state to prescribe, the pharmacist who is to fulfill the prescription shall establish that the prescription is authentic and that a bona fide relationship between the patient and the person prescribing the controlled substance did exist when the prescription was written. NRS 639.235(2)(b). A pharmacist who fills a prescription from an out-of-state prescriber shall record on the prescription or in the prescription record the details of the conversation. NRS 639.235(3).

19. Pharmacies that use a computerized system concerning prescriptions and that dispense controlled substances must transmit to the Board specific information including, among other information, the actual drug name (product ID). NAC 639.926.

20. The Drug Enforcement Administration outlines the requirements for electronic orders and prescriptions through 21 CFR Part 1311 Subpart C. Among other things, the system must require practitioners to use two-factor authentication when electronically submitting a prescriptions. 21 CFR § 1311.115; § 1311.120; § 1311.145. The pharmacy is responsible for ensuring that the pharmacy application imports, store, and displays the indication or signing and verifies the practitioner's electronic signature. 21 CFR § 1311.200(a).

21. A pharmacist shall not fill a prescription if the pharmacist has reason to believe that it was not issued in the usual course of the professional practice of a physician, physician assistant, dentist, advanced practice registered nurse, certified registered nurse anesthetist, podiatric physician, pharmacist registered pursuant to NRS 639.28079 or veterinarian. NRS 453.381(4).

22. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

23. Any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in its employ. NAC 639.945(3).

24. The Board may suspend or revoke any registration if the holder or applicant: 1) has violated, attempted to violate, assisted, or abetted in the violation of or conspired to violate any of the provisions of NRS chapter 639 or any law or regulation relating to drugs; or 2) is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4) and (12).

25. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

\\\

\\\

\\\

\\\

COUNT ONE

Unprofessional Conduct – Filling Prescriptions from Unlicensed Prescribers (Respondents VPI and Revive Rx)

26. As alleged above, during the relevant timeframe, Branch and Golden-Allen were not licensed to prescribe controlled substances in Nevada.

27. Respondents VPI and Revive Rx should have known that Branch was not licensed in Nevada based upon his out-of-state DEA number and other information on the prescriptions.

28. Respondent Revive Rx should have known that Golden-Allen was not licensed in Nevada based on her out-of-state DEA number and other information on the prescriptions.

29. Pursuant to NRS 639.235(2), Respondents Revive Rx and VPI had a duty to investigate the validity of Branch and/or Golden-Allen's prescriptions and failed to do so.

30. Respondents Revive Rx and VPI had a duty to reject prescriptions for controlled substances that they had reason to know were not issued in the ordinary course by a licensed practitioner for a legitimate medical purpose. NRS 453.381(4).

31. By filling controlled substance prescriptions prescribed by a practitioner not licensed to prescribe in Nevada, Respondents VPI and Revive Rx performed their duties in a negligent manner and engaged in unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(i),and are subject to discipline pursuant to NRS 639.210(4).

\\\

\\\

\\\

\\\

\\\

COUNT TWO
Unprofessional Conduct – Negligently Processing Non-Compliant Prescriptions (Respondent Revive Rx)

32. As alleged above, Revive Rx filled 1,104 controlled substance prescriptions transmitted from prescribers at Magnus and/or Young4Life, located at 8540 S. Eastern Avenue, Suite 160, in Las Vegas, Nevada, that were delivered to just 16 different addresses.

33. The prescriptions were written by eight different prescribers, two of whom were not licensed to prescribe controlled substances in Nevada. The unlicensed prescribers included Branch and Golden-Allen, who held DEA licenses that were not associated with an address in Nevada.

34. The patients for whom the prescriptions were written did not reside at the residential addresses where the prescriptions were delivered.

35. Based upon the conflicting information in the prescriptions and the large number of prescriptions received from a single source, Revive Rx knew or should have known that the patients listed on the prescription did not reside at the 16 different addresses.

36. Considered in totality, the above prescriptions contained sufficient information to put Revive Rx on notice that they were invalid, issued in violation of NAC 639.757, and/or not issued in the ordinary course for a legitimate medical purpose.

37. Revive Rx had a duty to exercise reasonable care to ensure that the above prescriptions were issued in compliance with applicable state and federal laws and not outside the ordinary course. NRS 453.380(4).

38. Revive Rx performed that duty in a negligent manner, thus engaging in unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(i).

COUNT THREE
Unprofessional Conduct – Negligently Processing Non-Compliant Prescriptions (Respondent Strive)

39. As alleged above, Strive filled at least sixty-four (64) prescriptions transmitted from prescribers at Magnus and/or Young4Life, located at 8540 S. Eastern Avenue, Suite 160, in Las Vegas, Nevada, that were delivered to just two addresses.

40. The prescriptions were written by three different prescribers, one of whom was not licensed to prescribe controlled substances in Nevada. The unlicensed prescriber was Branch, who held a DEA license that were not associated with an address in Nevada.

41. Once filled, 49 prescriptions for 8 patients were shipped by Strive to Magnus/Young4Life's address in Las Vegas.

42. Once filled, 15 prescriptions for 5 patients were shipped by Strive to the same residential street address in Las Vegas.

43. The patients for whom the prescriptions were written did not reside at the addresses.

44. Based upon the conflicting information in the prescriptions and the large number of prescriptions received from a single source, as well as corroboration by an internal investigation, Strive knew or should have known that the patients listed on the prescription did not reside at the addresses.

45. Considered in totality, the above prescriptions contained sufficient information to put Strive on notice that they were invalid, issued in violation of NAC 639.757, and/or not issued in the ordinary course for a legitimate medical purpose.

46. Strive had a duty to exercise reasonable care to ensure that the above prescriptions were issued in compliance with applicable state and federal laws and not outside the ordinary course. NRS 453.380(4).

47. Strive performed that duty in a negligent manner, thus engaging in unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(i).

COUNT FOUR
Violation of Federal Regulation Relating to Prescription Drugs/Non-compliance with ECPS
(Respondent Strive)

48. As alleged above, Strive did not have two-factor authentication in place for prescriber registrations and filled prescriptions that did not meet EPCS standards.

49. In filling prescriptions that did not comply with and were not submitted according to EPCS standards, Strive violated federal law. *See* 21 CFR § 1311.115; § 1311.120; § 1311.145; and 21 CFR § 1311.200(a).

50. By violating federal law, Strive is subject to discipline pursuant to NRS 639.210(11).

COUNT FIVE
Violation of State Law – Failing to Correctly Report Dispensations to the Prescription Monitoring Program
(Respondent VPI)

51. As alleged above, at least fifty-two (52) controlled substance prescriptions VPI reported to the Board's Prescription Monitoring Program (PMP) were listed as "compounded drug product" and did not indicate the active ingredient of the compounded controlled substance, in violation of NAC 639.926(e) and (g).

52. By violating NAC 639.926(e) and (g), VPI is subject to discipline pursuant to NRS 639.210(12).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of each of the Respondents herein.

DATED this 28th day of August 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **REVIVE RX,** **License No. PH04215,** **Respondent.**	**Case No. 24-482-PH-B-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 28th day of AUGUST 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **REVIVE RX,** **License No. PH04215,** **Respondent.**	**Case No. 24-482-PH-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

AUTHORIZED REPRESENTATIVE FOR REVIVE RX

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of August 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Revive Rx
3831 Golf Dr, #A
Houston, TX 77018

Philip E. Crooker, Esq.
Pistevo Law LLC
P.O. Box 339
Tigerville, South Carolina 29688

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

5P

FILED
AUG 2 8 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **VALESCENT PHARMACEUTICALS, INC., License No. PH04636,** **REVIVE RX, License No. PH04215, and** **STRIVE PHARMACY, License No. PH04562,** **Respondents.**	**Case No. 24-482-PH-A-S** **24-482-PH-B-S** **24-482-PH-C-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter and these respondents because, at the time of the events alleged herein, Respondent Valescent Pharmaceuticals, Inc. ("VPI") held a license issued by the Board to operate a pharmacy, License No. PH04636, Respondent Revive Rx ("Revive") held a license issued by the Board to operate a pharmacy, License No. PH04215, and Respondent Strive Pharmacy ("Strive") held a license issued by the Board to operate a pharmacy, License No. PH04562.

\\\

\\\

\\\

FACTUAL ALLEGATIONS

2. Since October 17, 2024, VPI, an out-of-state compounding pharmacy located at 7265 S. Revere Parkway, Suite 902, in Centennial, Colorado, has held a pharmacy license in Nevada issued by the Board.

3. Since April 6, 2020, Revive, an out-of-state compounding pharmacy located at 3831 Golf Drive #A, in Houston, Texas, has held a pharmacy license in Nevada issued by the Board.

4. Since February 8, 2024, Strive, an out-of-state compounding pharmacy located at 1275 E. Baseline Road #104, in Gilbert, Arizona, has held a pharmacy license in Nevada issued by the Board.

5. Since on or about March 2022, Magnus Medical Health and Wellness ("Magnus") was a clinic located 8540 S. Eastern Avenue, Suite 160, in Las Vegas, Nevada. On or about September 2024, Magnus was renamed Young4Life.

6. During the timeframe of its operation, Magnus and Young4Life employed at least eight practitioners who transmitted prescriptions for patients to Revive Rx, VPI, and Strive. Two of the practitioners, Paul Branch, MD ("Branch") and Juanita Golden-Allen, APRN ("Golden-Allen) were not licensed by the Board to prescribe dangerous drugs or controlled substances in Nevada.

7. A Board investigation found that Revive Rx dispensed a total of 700 prescriptions sent using Branch's prescribing credentials for controlled substances and dangerous drugs to Nevada patients of Magnus and Young4Life between December 2024 and February 2025. At that time, Branch was not registered by the Board to prescribe drugs in Nevada.

8. A Board investigation found that in May 2024, Revive Rx dispensed one hundred twenty-eight (128) controlled substance prescriptions submitted using Golden-Allen's credentials for ninety-nine (99) unique Nevada patients. At that time, Golden-Allen was not registered by the Board to prescribe controlled substances in Nevada.

9. A Board investigation found that, during the relevant timeframe, in total, Revive dispensed one thousand one hundred and four (1,104) controlled substance prescriptions from Magnus/Young4Life prescribers for five hundred and seventeen (517) unique patients to just sixteen (16) addresses in Las Vegas and Henderson. At least one of the addresses is Magnus/Young4Life's business address, and 15 addresses are residential addresses.

10. A Board investigation found that, during the relevant timeframe, forty-nine (49) controlled substance prescriptions for eight (8) different patients were sent to Magnus/Young4Life's business address and fifteen (15) controlled substance prescriptions for five (5) unique patients were sent to the same residential address. Strive's internal investigation confirmed that multiple prescriptions for unique Magnus/Young4Life patients were sent to the same address.

11. Furthermore, a Board investigation found that between February 2024 and November 2024, some electronic prescriptions Strive received were not compliant with Electronic Prescribing of Controlled Substances standards. Following discovery of the compliance issues, Strive confirmed the findings through an internal investigation and took action to implement stronger two-factor authentication procedures.

12. Because of these compliance issues, from February 2024 and November 2024, at least three prescribers for Magnus/Young4Life did not have two-factor authentication enabled and were not EPCS compliant.

13. A Board investigation found that between March 2025 and May 2025, VPI filled seven prescriptions for seven different Nevada patients from Branch. Branch did not hold a license issued by the Board to prescribe in Nevada.

14. Between March 2022 and March 2024, VPI filled one thousand eight hundred forty-six (1,845) controlled substance prescriptions for seven hundred fourteen (713) unique Nevada patients from Miller-Wilson. According to the PMP report, fifty-two (52) controlled substance prescriptions were listed as "compounded drug product" and did not indicate the active ingredient of the compounded controlled substance.

PRIOR DISCIPLINE

15. On December 3, 2025, the Board disciplined Respondent Revive Rx for dispensing non-FDA approved drugs. The Board placed Respondent Revive Rx on one-year probation beginning on December 3, 2025, and ordered it to pay a $5,000 fine and $4,000 in fees and costs. Additionally, the Board ordered every pharmacist and pharmaceutical technician who engaged in the practice of sterile compounding to complete training related to sterile compounding. The Board also ordered Revive Rx to undergo quarterly inspections by the Board, one inspection by the National Associations of Boards of Pharmacy, and to establish compounding policies and procedures in conformance with Nevada and federal law.

APPLICABLE LAW

16. Pursuant to NRS 639.100(1), it is unlawful for any person to possess, store, administer and/or dispense dangerous drugs without having secured the appropriate license and/or certificate of registration from the Board.

17. Only those individuals or practitioners permitted to do so pursuant to NRS 453.375 may possess, store, or administer controlled substances. Practitioners include physicians who hold a license to practice in their state and who are also registered by the Board to prescribe

controlled substances; advanced practice registered nurses who hold a certificate from the Board authorizing them to prescribe controlled substances; and physician assistants who hold a license from the Nevada State Board of Medical Examiners and are authorized by the Board to prescribe controlled substances under the supervision of physician. NRS 453.126.

18. Pursuant to NRS 639.235(1), no person other than a practitioner holding a license to practice his or her profession in Nevada may prescribe or write a prescription, except that a prescription written by a person who is not licensed to practice in Nevada, but is authorized by the laws of another state to prescribe. If a prescription for a Schedule III controlled substance that is prescribed by a person who is not licensed to practice in Nevada, but is authorized by the laws of another state to prescribe, the pharmacist who is to fulfill the prescription shall establish that the prescription is authentic and that a bona fide relationship between the patient and the person prescribing the controlled substance did exist when the prescription was written. NRS 639.235(2)(b). A pharmacist who fills a prescription from an out-of-state prescriber shall record on the prescription or in the prescription record the details of the conversation. NRS 639.235(3).

19. Pharmacies that use a computerized system concerning prescriptions and that dispense controlled substances must transmit to the Board specific information including, among other information, the actual drug name (product ID). NAC 639.926.

20. The Drug Enforcement Administration outlines the requirements for electronic orders and prescriptions through 21 CFR Part 1311 Subpart C. Among other things, the system must require practitioners to use two-factor authentication when electronically submitting a prescriptions. 21 CFR § 1311.115; § 1311.120; § 1311.145. The pharmacy is responsible for ensuring that the pharmacy application imports, store, and displays the indication or signing and verifies the practitioner's electronic signature. 21 CFR § 1311.200(a).

21. A pharmacist shall not fill a prescription if the pharmacist has reason to believe that it was not issued in the usual course of the professional practice of a physician, physician assistant, dentist, advanced practice registered nurse, certified registered nurse anesthetist, podiatric physician, pharmacist registered pursuant to NRS 639.28079 or veterinarian. NRS 453.381(4).

22. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

23. Any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in its employ. NAC 639.945(3).

24. The Board may suspend or revoke any registration if the holder or applicant: 1) has violated, attempted to violate, assisted, or abetted in the violation of or conspired to violate any of the provisions of NRS chapter 639 or any law or regulation relating to drugs; or 2) is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4) and (12).

25. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

\\\

\\\

\\\

\\\

COUNT ONE

Unprofessional Conduct – Filling Prescriptions from Unlicensed Prescribers (Respondents VPI and Revive Rx)

26. As alleged above, during the relevant timeframe, Branch and Golden-Allen were not licensed to prescribe controlled substances in Nevada.

27. Respondents VPI and Revive Rx should have known that Branch was not licensed in Nevada based upon his out-of-state DEA number and other information on the prescriptions.

28. Respondent Revive Rx should have known that Golden-Allen was not licensed in Nevada based on her out-of-state DEA number and other information on the prescriptions.

29. Pursuant to NRS 639.235(2), Respondents Revive Rx and VPI had a duty to investigate the validity of Branch and/or Golden-Allen's prescriptions and failed to do so.

30. Respondents Revive Rx and VPI had a duty to reject prescriptions for controlled substances that they had reason to know were not issued in the ordinary course by a licensed practitioner for a legitimate medical purpose. NRS 453.381(4).

31. By filling controlled substance prescriptions prescribed by a practitioner not licensed to prescribe in Nevada, Respondents VPI and Revive Rx performed their duties in a negligent manner and engaged in unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(i),and are subject to discipline pursuant to NRS 639.210(4).

\\\

\\\

\\\

\\\

\\\

COUNT TWO
Unprofessional Conduct – Negligently Processing Non-Compliant Prescriptions (Respondent Revive Rx)

32. As alleged above, Revive Rx filled 1,104 controlled substance prescriptions transmitted from prescribers at Magnus and/or Young4Life, located at 8540 S. Eastern Avenue, Suite 160, in Las Vegas, Nevada, that were delivered to just 16 different addresses.

33. The prescriptions were written by eight different prescribers, two of whom were not licensed to prescribe controlled substances in Nevada. The unlicensed prescribers included Branch and Golden-Allen, who held DEA licenses that were not associated with an address in Nevada.

34. The patients for whom the prescriptions were written did not reside at the residential addresses where the prescriptions were delivered.

35. Based upon the conflicting information in the prescriptions and the large number of prescriptions received from a single source, Revive Rx knew or should have known that the patients listed on the prescription did not reside at the 16 different addresses.

36. Considered in totality, the above prescriptions contained sufficient information to put Revive Rx on notice that they were invalid, issued in violation of NAC 639.757, and/or not issued in the ordinary course for a legitimate medical purpose.

37. Revive Rx had a duty to exercise reasonable care to ensure that the above prescriptions were issued in compliance with applicable state and federal laws and not outside the ordinary course. NRS 453.380(4).

38. Revive Rx performed that duty in a negligent manner, thus engaging in unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(i).

COUNT THREE

Unprofessional Conduct – Negligently Processing Non-Compliant Prescriptions (Respondent Strive)

39. As alleged above, Strive filled at least sixty-four (64) prescriptions transmitted from prescribers at Magnus and/or Young4Life, located at 8540 S. Eastern Avenue, Suite I60, in Las Vegas, Nevada, that were delivered to just two addresses.

40. The prescriptions were written by three different prescribers, one of whom was not licensed to prescribe controlled substances in Nevada. The unlicensed prescriber was Branch, who held a DEA license that were not associated with an address in Nevada.

41. Once filled, 49 prescriptions for 8 patients were shipped by Strive to Magnus/Young4Life's address in Las Vegas.

42. Once filled, 15 prescriptions for 5 patients were shipped by Strive to the same residential street address in Las Vegas.

43. The patients for whom the prescriptions were written did not reside at the addresses.

44. Based upon the conflicting information in the prescriptions and the large number of prescriptions received from a single source, as well as corroboration by an internal investigation, Strive knew or should have known that the patients listed on the prescription did not reside at the addresses.

45. Considered in totality, the above prescriptions contained sufficient information to put Strive on notice that they were invalid, issued in violation of NAC 639.757, and/or not issued in the ordinary course for a legitimate medical purpose.

46. Strive had a duty to exercise reasonable care to ensure that the above prescriptions were issued in compliance with applicable state and federal laws and not outside the ordinary course. NRS 453.380(4).

47. Strive performed that duty in a negligent manner, thus engaging in unprofessional conduct for which the Board may impose administrative discipline. *See* NRS 639.210(4); NAC 639.945(1)(i).

COUNT FOUR
Violation of Federal Regulation Relating to Prescription Drugs/Non-compliance with ECPS
(Respondent Strive)

48. As alleged above, Strive did not have two-factor authentication in place for prescriber registrations and filled prescriptions that did not meet EPCS standards.

49. In filling prescriptions that did not comply with and were not submitted according to EPCS standards, Strive violated federal law. *See* 21 CFR § 1311.115; § 1311.120; § 1311.145; and 21 CFR § 1311.200(a).

50. By violating federal law, Strive is subject to discipline pursuant to NRS 639.210(11).

COUNT FIVE
Violation of State Law – Failing to Correctly Report Dispensations to the Prescription Monitoring Program
(Respondent VPI)

51. As alleged above, at least fifty-two (52) controlled substance prescriptions VPI reported to the Board's Prescription Monitoring Program (PMP) were listed as "compounded drug product" and did not indicate the active ingredient of the compounded controlled substance, in violation of NAC 639.926(e) and (g).

52. By violating NAC 639.926(e) and (g), VPI is subject to discipline pursuant to NRS 639.210(12).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of each of the Respondents herein.

DATED this 24th day of August 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **STRIVE PHARMACY,** **License No. PH04562,** **Respondent.**	**Case No. 24-482-PH-C-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 28th day of AUGUST 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **STRIVE PHARMACY,** **License No. PH04562,** **Respondent.**	**Case No. 24-482-PH-C-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

AUTHORIZED REPRESENTATIVE FOR STRIVE PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of August 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Strive Pharmacy
1275 E Baseline Rd #104
Gilbert, AZ 85233

Alexander Snyder, Esq.
Quarles & Brady LLP
One Renaissance Square
Two North Central Ave Suite 600
Phoenix, AZ 85004

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

5Q

FILED
AUG 28 2026
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

MIKAYLA STRIEF, APRN
Certificate of Registration No. CS37751,

JUSTIN SPANGLER, PA
Certificate of Registration No. CS28770,

DANIEL INGLISH, DO
Certificate of Registration No. CS22888,

MARY MILLER-WILSON, APRN
Certificate of Registration No. CS33703,

MARK BERNARDI, MD
Certificate of Registration No. CS29595, and

TIANA HUBBARD, APRN
Certificate of Registration No. CS25791,

Respondents.

Case Nos. 24-482-CS-A-S
24-482-CS-B-S
24-482-CS-C-S
24-482-CS-D-S
24-482-CS-E-S
24-482-CS-F-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter and these respondents because, at the time of the events alleged herein, Justin Spangler, PA ("Spangler") held a registration issued by the Board, Certificate of Registration No. CS28770; Mikayla Strief, APRN ("Strief") held a registration issued by the Board, Certificate of Registration No. CS37751; Daniel Inglish, DO ("Inglish") held a registration issued by the

Board, Certificate of Registration No. CS22888; Mary Miller-Wilson, APRN ("Miller-Wilson") held a registration issued by the Board, Certificate of Registration No. CS33703; Mark Bernardi, MD ("Bernardi") held a registration issued by the Board, Certificate of Registration No. CS29595; and Tiana Hubbard, APRN ("Hubbard") held a registration issued by the Board, Certificate of Registration No. CS25791.

FACTUAL ALLEGATIONS

2. Respondent Spangler is licensed by the Nevada State Board of Medical Examiners as a physician assistant. At the time of the violations alleged herein, Spangler was a "practitioner" as that term is defined at NRS 453.126(5) and 639.0125(4).

3. Respondents Strief, Miller-Wilson, and Hubbard are licensed by the Nevada State Board of Nursing as advanced practice registered nurses. At the time of the violations alleged herein, Strief, Miller-Wilson, and Hubbard were "practitioners" as that term is defined at NRS 453.126(2) and 639.0125(3).

4. Respondent Inglish is licensed by the Nevada State Board of Osteopathic Medicine as an osteopathic physician. At the time of the violations alleged herein, Inglish was a "practitioner" as that term is defined at NRS 453.126(1) and 639.0125(1).

5. Respondent Bernardi is licensed by the Nevada State Board of Medical Examiners as a physician. At the time of the violations alleged herein, Bernardi was a "practitioner" as that term is defined at NRS 453.126(1) and 639.0125(1).

6. On or about March 2022, David Lindberg ("Lindberg") began operating the wellness clinic D.C.L., LLC, dba Magnus Medical Health and Wellness ("Magnus"), located at 8540 S. Eastern Avenue, Suite 160, in Las Vegas, Nevada. Lindberg is not a licensed practitioner as that term is defined at NRS 453.126(1) and 639.0125(1) and not licensed by the Board or the

Federal Drug Enforcement Administration ("DEA") to possess, administer, prescribe or dispense dangerous drugs or controlled substances.

7. During the relevant timeframe, Respondents Spangler, Strief, Miller-Wilson, Inglish, and Hubbard worked as practitioners at Magnus.

8. On or about September 2024, Lindberg sold Magnus to new owners Donald Min ("Min") and Young Kim ("Kim"), who renamed the business Young4Life. Neither Min nor Kim are licensed practitioners as that term is defined at NRS 453.126(1) and 639.0125(1) or licensed by the Board or DEA to possess, administer, prescribe or dispense dangerous drugs or controlled substances.

9. Min and Kim formed Young4Life in late 2024 and assumed Magnus's established customers and business model. Young4Life retained Lindberg as a marketing consultant.

10. During the relevant timeframe, Respondents Spangler and Bernardi worked as practitioners at Young4Life.

11. A Board investigation found that, as owner of Magnus, between September 2022 and September 2024, Lindberg regularly used several Magnus employees' prescribing credentials to issue prescriptions and access prescribing systems. From September 2024 through at least May 2025, as marketing consultant, Lindberg continued using Young4Life employee's prescribing credentials to issue prescriptions and access prescribing systems.

12. Specifically, during the relevant timeframe, each Respondent permitted Lindberg to access prescribing systems and issue the following controlled substance prescriptions using their electronic prescribing credentials:

A. According to Board records, between May 2024 and November 2024, while employed by Magnus and Young4Life, Spangler authorized 548 controlled

substance prescriptions for 397 unique patients. Furthermore, according to the Board's records, Spangler did not access the PMP database to review his own prescribing activity ("MyRx report") from September 2019 to July 18, 2025. Spangler has only run one patient PMP query, in October 2019.

B. Between May 2024 and November 2024, while employed by Magnus, Strief authorized 170 controlled substance prescriptions for Nevada patients. Strief checked her MyRx report only one time, in December 2024. Strief also did not run any patient PMP queries prior to December 2024.

C. Per company policy, Strief delegated the entire prescribing process to Magnus. As such, Strief sent her prescribing token to Magnus and did not personally authorize any prescriptions for armodafinil, chorionic gonad or ketamine that appeared on her prescribing report from April to November 2024.

D. Between May 2024 and May 2025, while employed by Magnus, Inglish prescribed 63 controlled substances for Nevada patients. Inglish checked his MyRx report two times, in April 2025 and August 2025. He did not check it prior to that date. Inglish has not run any patient PMP queries since June 2022.

E. Between March 2022 and March 2024, while employed by Magnus, Miller-Wilson prescribed 1,846 controlled substances for 714 unique Nevada patients. Miller-Wilson checked her MyRx report once in October 2023. She has been compliant in checking her MyRx report since October 2024.

F. Per company policy, Miller-Wilson delegated the entire prescribing process to Magnus.

G. Between February 2025 and June 25, 2025, while employed by Young4Life, Bernardi prescribed 327 controlled substances for 203 unique Nevada patients. Bernardi has not checked his MyRx report from June 2022 and July 2025. Bernardi did not run any patient PMP queries prior to August 4, 2025.

H. Per company policy at Young4Life, Spangler or another physician's assistant would evaluate patients, generally via telehealth. Bernardi would then sign off on patient charts and prescriptions that were sent via his electronic credentials. Bernardi delegated the issuing of electronic prescriptions to someone else at Young4Life.

I. Between February 2023 and March 2024, while employed by Magnus, Hubbard prescribed 381 controlled substances for 202 unique Nevada patients. Hubbard checked her MyRx report only one time, in October 2024. She has not run any patient PMP queries between April 2019 and May 2025.

13. Between June 30, 2025 through August 20, 2025, Board Investigator Dena McClish (McClish) attempted to communicate with Bernardi to discuss his patient records and employment at Young4Life. Although Bernardi indicated that he would cooperate with McClish's investigation, he ultimately failed to respond to her requests for information.

14. On or about July 1, 2025, McClish attempted to contact Hubbard through certified and regular U.S. Mail and e-mail about her patient records and employment with Magnus. Hubbard failed to respond to her requests for information.

\\\

\\\

\\\

PRIOR DISCIPLINE

15. On December 3, 2025, the Board disciplined Respondent Inglish for allowing unlicensed individuals independent access to dangerous drugs; allowing unlicensed individuals to access, possess, furnish, and administer dangerous drugs; permitting the administration of patient-specific prescription medications to multiple patients; intermingling of adulterated and expired drugs; falsifying prescriptions; and aiding and abetting unlicensed practice. The Board placed Respondent Inglish on one-year probation beginning on December 3, 2025, and ordered him to pay a $5,000 fine and $1,000 in fees and costs.

APPLICABLE LAW

16. Pursuant to NRS 639.100(1), it is unlawful for any person to manufacture, engage in wholesale distribution, compound, sell or dispense, or permit to be manufactured, distributed at wholesale, compounded, sold or dispensed, any drug, poison, medicine or chemical, or to dispense or compound, or permit to be dispensed or compounded drugs without having secured the appropriate license and/or certificate of registration from the Board.

17. Falsifying a prescription for a controlled substance is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1).

18. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession, to a patient with whom the practitioner has established a bona fide therapeutic relationship. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a); 21 CFR § 1306.04(a); NRS 453.381(1); NRS 639.235(1); NRS 639.23911(1)(a); NRS 639.2813(1).

19. A practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor, or biometric information, with any other person. The practitioner must not allow any other person to use the token or enter the knowledge factor or other identification means to sign prescriptions for controlled substances. 21 CFR § 1311.102 and NAC 639.7105(2)(b).

20. The Controlled Substances Act imposes strict liability on registrants to provide effective controls and procedures to guard against theft and diversion, which includes the duty to safeguard prescribing credentials from unauthorized use. *See* 21 CFR 1301.71(a). 21 U.S.C. § 843(a)(2) criminalizes the use of another person's DEA registration number

21. A practitioner shall, before issuing an initial prescription for a controlled substance, and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the PMP. NRS 639.23507.

22. A practitioner registered with the Board to write prescriptions for controlled substances must access his or her prescriber activity in the PMP at least once every 6 months to review prescriptions issued by the practitioner and to verify for the Board that he or she continues to have access to the PMP. NRS 453.164(7).

23. Any licensee registered with the Board must provide access to all records of sale and disposition of drugs, medicines or poisons or devices or appliances that are restricted by federal law to sale by or on the order of a physician, to members of the Board, its inspectors, and investigators. NRS 639.090. *See also* NRS 639.239 (duty to provide prescription records); NRS 453.246 (records related to controlled substances).

24. Every practitioner who engages in the practicing of furnishing dangerous drugs to patients shall maintain a complete and accurate record of all dangerous drugs purchased and those sold on prescription, dispensed, furnished or disposed of otherwise. NRS 454.286(1). The records must be retained for a period of 2 years and must be open to inspection by members, inspectors or investigators of the Board. NRS 454.286(2). *See also* 21 U.S.C. § 827 (recordkeeping requirements by registrants); 21 CFR § 1304.06 and 21 CFR § 1311.305 (regarding electronic prescription records).

25. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1)(e) and NRS 639.210(4).

26. Prescribing a drug to any patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n)(2) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4). A bona fide relationship shall be deemed to exist if the patient was examined in person, electronically, telephonically or by fiber optics within or outside of this State or the United States by the practitioner within the 6 months immediately preceding the date the prescription was issued. NAC 639.752.

27. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

28. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

29. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

30. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

31. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 upon a finding that the registrant has committed an act that renders registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Unprofessional Conduct -Party to Fraudulent or Deceitful Practice or Transaction by Permitting Use of Credentials
(All Respondents)

32. As alleged above, by permitting Lindberg to use their credentials and act under their authority to fraudulently issue prescriptions for controlled substances, each Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(l)(e), NRS 453.241(1) and/or NRS 639.210(4).

\\\

\\\

COUNT TWO

Unprofessional Conduct -Incompetent, Unskillful or Negligent Performance of Duties by Allowing Prescribing Credentials to be Compromised
(All Respondents)

33. As alleged above, to the extent each Respondent's electronic prescribing credentials were compromised and resulted in the unlawful issuance of fraudulent controlled substance prescriptions by a third party, Respondents failed to comply with 21 CFR § 1311.102, NRS 453.164(7) and NAC 639.7105(2)(b), performed their duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner, and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), committed acts that render their registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(4), (11) and (12).

COUNT THREE

Violations of Federal Controlled Substances Act – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(All Respondents)

34. As alleged above, by permitting Lindberg to use their credentials and act under their authority to issue electronic prescriptions for controlled substances, each Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR 1301.71(a). 21 U.S.C. § 843(a)(2),21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 846, 21 CFR § 1306.03(a), 21 CFR § 1306.04(a), 21 CFR § 1311.100 and/or 21 CFR § 1311.102 and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1) and/or NRS 639.210(11).

\\\

\\\

\\\

COUNT FOUR

Unprofessional Conduct – Assisting or abetting unlicensed practice
(All Respondents)

35. As alleged above, Lindberg did not have licensure from the Board as required by NRS 639.100(1) when he used each Respondent's credential and acted under their authority to issue electronic prescriptions for controlled substances.

36. By assisting and abetting Lindberg's unlicensed activity, each Respondent engaged in unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(j), and is subject to discipline pursuant to NRS 639.210(4).

COUNT FIVE

Violations of State Law – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(All Respondents)

37. As alleged above, by permitting Lindberg to use their credentials and act under their authority to issue electronic prescriptions for controlled substances, each Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.381(1), NRS 453.385, NRS 453.401(l)(a), NRS 639.235(1), NRS 639.23535, NRS 639.23911(1)(a), NRS 639.2813(1) and/or NAC 639.7105, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT SIX

Unprofessional Conduct by a Practitioner – Failure to Query PMP Database
(All Respondents)

38. As alleged above, each Respondent failed to query the PMP database regarding his or her patients' histories of using controlled substances as required by law. NRS 639.23507.

39. As alleged above, each Respondent failed to query the PMP database regarding his or her own prescriber activity as required by law. NRS 453.164(7).

40. By failing to query the PMP database to review their patients' utilization reports prior to issuing a prescription for a controlled substance, and by failing to review their own prescriber activity on a semi-annual basis, Respondents violated NRS 453.164(7) and NRS 639.23507.

41. Furthermore, by failing to query the PMP database to review their patients' utilization report prior to issuing a prescription for a controlled substance, and by failing to review their own prescriber activity on a semi-annual basis, each Respondent performed his or her duties as the holder of a certificate issued by the Board in an incompetent, unskillful or negligent manner.

42. As alleged above, each Respondent's conduct constitutes unprofessional conduct for which the Board may impose administrative discipline. NRS 639.210(4); NAC 639.945(1)(i).

COUNT SEVEN
Unprofessional Conduct – Prescribing Without Bona Fide Therapeutic Relationship
(Respondent Bernardi)

43. As alleged above, during the course of Bernardi's employment with Young4Life, a physician's assistant evaluated patients either in-person or via telehealth, and Bernardi reviewed and signed off on patient charts and prescriptions sent under his name.

44. By failing to personally evaluate patients for whom he prescribed controlled substances, Bernardi did not form a bona fide therapeutic relationship as defined in NAC 639.752(4).

45. By permitting the use of his credentials to issue electronic prescriptions for controlled substances to patients with whom he did not have a bona fide therapeutic relationship, Respondent Bernardi engaged in unprofessional conduct and conduct contrary to the public

interest as defined in NAC 639.945(1)(n)(2), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT EIGHT
Violations of Federal and State Law – Recordkeeping
(Respondents Bernardi and Hubbard)

46. As alleged above, by failing to respond to a Board investigator's requests for information and records related to an investigation into their prescribing activities, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.090, NRS 454.286(2), NRS 453.246, NRS 639.239, 21 U.S.C. § 827, 21 CFR § 1311.120(28), 21 CFR § 1304.06, 21 CFR § 1311.305, and 21 CFR § 1311.305, and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11) and/or (12).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of each of the Respondents herein.

DATED this 2nd day of AUGUST 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **Mikayla Strief, APRN** **Certificate of Registration No. CS37751,** **JUSTIN SPANGLER, PA** **Certificate of Registration No. CS28770,** **DANIEL INGLISH, DO** **Certificate of Registration No. CS22888,** **Mary Miller-Wilson, APRN** **Certificate of Registration No. CS33703,** **MARK BERNARDI, MD** **Certificate of Registration No. CS29595, and** **TIANA HUBBARD, APRN** **Certificate of Registration No. CS25791,** **Respondents.**	**Case Nos. 24-482-CS-A-S** **24-482-CS-B-S** **24-482-CS-C-S** **24-482-CS-D-S** **24-482-CS-E-S** **24-482-CS-F-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the

Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of AUGUST 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MIKAYLA STRIEF, APRN** **Certificate of Registration No. CS37751,** **Respondent.**	**Case No. 24-482-CS-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

MIKAYLA STRIEF, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of August 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Mikayla Strief, APRN
c/o Magnus Medical Health and Wellness
8540 S Eastern Ave., Ste. 160
Las Vegas, NV 89123

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

5R

FILED
AUG 28 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MIKAYLA STRIEF, APRN** **Certificate of Registration No. CS37751,** **JUSTIN SPANGLER, PA** **Certificate of Registration No. CS28770,** **DANIEL INGLISH, DO** **Certificate of Registration No. CS22888,** **MARY MILLER-WILSON, APRN** **Certificate of Registration No. CS33703,** **MARK BERNARDI, MD** **Certificate of Registration No. CS29595, and** **TIANA HUBBARD, APRN** **Certificate of Registration No. CS25791,** **Respondents.**	**Case Nos. 24-482-CS-A-S** **24-482-CS-B-S** **24-482-CS-C-S** **24-482-CS-D-S** **24-482-CS-E-S** **24-482-CS-F-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter and these respondents because, at the time of the events alleged herein, Justin Spangler, PA ("Spangler") held a registration issued by the Board, Certificate of Registration No. CS28770; Mikayla Strief, APRN ("Strief") held a registration issued by the Board, Certificate of Registration No. CS37751; Daniel Inglish, DO ("Inglish") held a registration issued by the

Board, Certificate of Registration No. CS22888; Mary Miller-Wilson, APRN ("Miller-Wilson") held a registration issued by the Board, Certificate of Registration No. CS33703; Mark Bernardi, MD ("Bernardi") held a registration issued by the Board, Certificate of Registration No. CS29595; and Tiana Hubbard, APRN ("Hubbard") held a registration issued by the Board, Certificate of Registration No. CS25791.

FACTUAL ALLEGATIONS

2. Respondent Spangler is licensed by the Nevada State Board of Medical Examiners as a physician assistant. At the time of the violations alleged herein, Spangler was a "practitioner" as that term is defined at NRS 453.126(5) and 639.0125(4).

3. Respondents Strief, Miller-Wilson, and Hubbard are licensed by the Nevada State Board of Nursing as advanced practice registered nurses. At the time of the violations alleged herein, Strief, Miller-Wilson, and Hubbard were "practitioners" as that term is defined at NRS 453.126(2) and 639.0125(3).

4. Respondent Inglish is licensed by the Nevada State Board of Osteopathic Medicine as an osteopathic physician. At the time of the violations alleged herein, Inglish was a "practitioner" as that term is defined at NRS 453.126(1) and 639.0125(1).

5. Respondent Bernardi is licensed by the Nevada State Board of Medical Examiners as a physician. At the time of the violations alleged herein, Bernardi was a "practitioner" as that term is defined at NRS 453.126(1) and 639.0125(1).

6. On or about March 2022, David Lindberg ("Lindberg") began operating the wellness clinic D.C.L., LLC, dba Magnus Medical Health and Wellness ("Magnus"), located at 8540 S. Eastern Avenue, Suite 160, in Las Vegas, Nevada. Lindberg is not a licensed practitioner as that term is defined at NRS 453.126(1) and 639.0125(1) and not licensed by the Board or the

Federal Drug Enforcement Administration ("DEA") to possess, administer, prescribe or dispense dangerous drugs or controlled substances.

7. During the relevant timeframe, Respondents Spangler, Strief, Miller-Wilson, Inglish, and Hubbard worked as practitioners at Magnus.

8. On or about September 2024, Lindberg sold Magnus to new owners Donald Min ("Min") and Young Kim ("Kim"), who renamed the business Young4Life. Neither Min nor Kim are licensed practitioners as that term is defined at NRS 453.126(1) and 639.0125(1) or licensed by the Board or DEA to possess, administer, prescribe or dispense dangerous drugs or controlled substances.

9. Min and Kim formed Young4Life in late 2024 and assumed Magnus's established customers and business model. Young4Life retained Lindberg as a marketing consultant.

10. During the relevant timeframe, Respondents Spangler and Bernardi worked as practitioners at Young4Life.

11. A Board investigation found that, as owner of Magnus, between September 2022 and September 2024, Lindberg regularly used several Magnus employees' prescribing credentials to issue prescriptions and access prescribing systems. From September 2024 through at least May 2025, as marketing consultant, Lindberg continued using Young4Life employee's prescribing credentials to issue prescriptions and access prescribing systems.

12. Specifically, during the relevant timeframe, each Respondent permitted Lindberg to access prescribing systems and issue the following controlled substance prescriptions using their electronic prescribing credentials:

A. According to Board records, between May 2024 and November 2024, while employed by Magnus and Young4Life, Spangler authorized 548 controlled

substance prescriptions for 397 unique patients. Furthermore, according to the Board's records, Spangler did not access the PMP database to review his own prescribing activity ("MyRx report") from September 2019 to July 18, 2025. Spangler has only run one patient PMP query, in October 2019.

B. Between May 2024 and November 2024, while employed by Magnus, Strief authorized 170 controlled substance prescriptions for Nevada patients. Strief checked her MyRx report only one time, in December 2024. Strief also did not run any patient PMP queries prior to December 2024.

C. Per company policy, Strief delegated the entire prescribing process to Magnus. As such, Strief sent her prescribing token to Magnus and did not personally authorize any prescriptions for armodafinil, chorionic gonad or ketamine that appeared on her prescribing report from April to November 2024.

D. Between May 2024 and May 2025, while employed by Magnus, Inglish prescribed 63 controlled substances for Nevada patients. Inglish checked his MyRx report two times, in April 2025 and August 2025. He did not check it prior to that date. Inglish has not run any patient PMP queries since June 2022.

E. Between March 2022 and March 2024, while employed by Magnus, Miller-Wilson prescribed 1,846 controlled substances for 714 unique Nevada patients. Miller-Wilson checked her MyRx report once in October 2023. She has been compliant in checking her MyRx report since October 2024.

F. Per company policy, Miller-Wilson delegated the entire prescribing process to Magnus.

G. Between February 2025 and June 25, 2025, while employed by Young4Life, Bernardi prescribed 327 controlled substances for 203 unique Nevada patients. Bernardi has not checked his MyRx report from June 2022 and July 2025. Bernardi did not run any patient PMP queries prior to August 4, 2025.

H. Per company policy at Young4Life, Spangler or another physician's assistant would evaluate patients, generally via telehealth. Bernardi would then sign off on patient charts and prescriptions that were sent via his electronic credentials. Bernardi delegated the issuing of electronic prescriptions to someone else at Young4Life.

I. Between February 2023 and March 2024, while employed by Magnus, Hubbard prescribed 381 controlled substances for 202 unique Nevada patients. Hubbard checked her MyRx report only one time, in October 2024. She has not run any patient PMP queries between April 2019 and May 2025.

13. Between June 30, 2025 through August 20, 2025, Board Investigator Dena McClish (McClish) attempted to communicate with Bernardi to discuss his patient records and employment at Young4Life. Although Bernardi indicated that he would cooperate with McClish's investigation, he ultimately failed to respond to her requests for information.

14. On or about July 1, 2025, McClish attempted to contact Hubbard through certified and regular U.S. Mail and e-mail about her patient records and employment with Magnus. Hubbard failed to respond to her requests for information.

\\\

\\\

\\\

PRIOR DISCIPLINE

15. On December 3, 2025, the Board disciplined Respondent Inglish for allowing unlicensed individuals independent access to dangerous drugs; allowing unlicensed individuals to access, possess, furnish, and administer dangerous drugs; permitting the administration of patient-specific prescription medications to multiple patients; intermingling of adulterated and expired drugs; falsifying prescriptions; and aiding and abetting unlicensed practice. The Board placed Respondent Inglish on one-year probation beginning on December 3, 2025, and ordered him to pay a $5,000 fine and $1,000 in fees and costs.

APPLICABLE LAW

16. Pursuant to NRS 639.100(1), it is unlawful for any person to manufacture, engage in wholesale distribution, compound, sell or dispense, or permit to be manufactured, distributed at wholesale, compounded, sold or dispensed, any drug, poison, medicine or chemical, or to dispense or compound, or permit to be dispensed or compounded drugs without having secured the appropriate license and/or certificate of registration from the Board.

17. Falsifying a prescription for a controlled substance is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1).

18. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession, to a patient with whom the practitioner has established a bona fide therapeutic relationship. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a); 21 CFR § 1306.04(a); NRS 453.381(1); NRS 639.235(1); NRS 639.23911(1)(a); NRS 639.2813(1).

19. A practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor, or biometric information, with any other person. The practitioner must not allow any other person to use the token or enter the knowledge factor or other identification means to sign prescriptions for controlled substances. 21 CFR § 1311.102 and NAC 639.7105(2)(b).

20. The Controlled Substances Act imposes strict liability on registrants to provide effective controls and procedures to guard against theft and diversion, which includes the duty to safeguard prescribing credentials from unauthorized use. *See* 21 CFR 1301.71(a). 21 U.S.C. § 843(a)(2) criminalizes the use of another person's DEA registration number

21. A practitioner shall, before issuing an initial prescription for a controlled substance, and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the PMP. NRS 639.23507.

22. A practitioner registered with the Board to write prescriptions for controlled substances must access his or her prescriber activity in the PMP at least once every 6 months to review prescriptions issued by the practitioner and to verify for the Board that he or she continues to have access to the PMP. NRS 453.164(7).

23. Any licensee registered with the Board must provide access to all records of sale and disposition of drugs, medicines or poisons or devices or appliances that are restricted by federal law to sale by or on the order of a physician, to members of the Board, its inspectors, and investigators. NRS 639.090. *See also* NRS 639.239 (duty to provide prescription records); NRS 453.246 (records related to controlled substances).

24. Every practitioner who engages in the practicing of furnishing dangerous drugs to patients shall maintain a complete and accurate record of all dangerous drugs purchased and those sold on prescription, dispensed, furnished or disposed of otherwise. NRS 454.286(1). The records must be retained for a period of 2 years and must be open to inspection by members, inspectors or investigators of the Board. NRS 454.286(2). *See also* 21 U.S.C. § 827 (recordkeeping requirements by registrants); 21 CFR § 1304.06 and 21 CFR § 1311.305 (regarding electronic prescription records).

25. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1)(e) and NRS 639.210(4).

26. Prescribing a drug to any patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n)(2) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4). A bona fide relationship shall be deemed to exist if the patient was examined in person, electronically, telephonically or by fiber optics within or outside of this State or the United States by the practitioner within the 6 months immediately preceding the date the prescription was issued. NAC 639.752.

27. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

28. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

29. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

30. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

31. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 upon a finding that the registrant has committed an act that renders registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Unprofessional Conduct -Party to Fraudulent or Deceitful Practice or Transaction by Permitting Use of Credentials
(All Respondents)

32. As alleged above, by permitting Lindberg to use their credentials and act under their authority to fraudulently issue prescriptions for controlled substances, each Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(l)(e), NRS 453.241(1) and/or NRS 639.210(4).

\\\

\\\

COUNT TWO

Unprofessional Conduct -Incompetent, Unskillful or Negligent Performance of Duties by Allowing Prescribing Credentials to be Compromised
(All Respondents)

33. As alleged above, to the extent each Respondent's electronic prescribing credentials were compromised and resulted in the unlawful issuance of fraudulent controlled substance prescriptions by a third party, Respondents failed to comply with 21 CFR § 1311.102, NRS 453.164(7) and NAC 639.7105(2)(b), performed their duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner, and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), committed acts that render their registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(4), (11) and (12).

COUNT THREE

Violations of Federal Controlled Substances Act – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(All Respondents)

34. As alleged above, by permitting Lindberg to use their credentials and act under their authority to issue electronic prescriptions for controlled substances, each Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR 1301.71(a). 21 U.S.C. § 843(a)(2),21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 846, 21 CFR § 1306.03(a), 21 CFR § 1306.04(a), 21 CFR § 1311.100 and/or 21 CFR § 1311.102 and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1) and/or NRS 639.210(11).

\\\

\\\

\\\

COUNT FOUR

Unprofessional Conduct – Assisting or abetting unlicensed practice
(All Respondents)

35. As alleged above, Lindberg did not have licensure from the Board as required by NRS 639.100(1) when he used each Respondent's credential and acted under their authority to issue electronic prescriptions for controlled substances.

36. By assisting and abetting Lindberg's unlicensed activity, each Respondent engaged in unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(j), and is subject to discipline pursuant to NRS 639.210(4).

COUNT FIVE

Violations of State Law – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(All Respondents)

37. As alleged above, by permitting Lindberg to use their credentials and act under their authority to issue electronic prescriptions for controlled substances, each Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.381(1), NRS 453.385, NRS 453.401(l)(a), NRS 639.235(1), NRS 639.23535, NRS 639.23911(1)(a), NRS 639.2813(1) and/or NAC 639.7105, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT SIX

Unprofessional Conduct by a Practitioner – Failure to Query PMP Database
(All Respondents)

38. As alleged above, each Respondent failed to query the PMP database regarding his or her patients' histories of using controlled substances as required by law. NRS 639.23507.

39. As alleged above, each Respondent failed to query the PMP database regarding his or her own prescriber activity as required by law. NRS 453.164(7).

40. By failing to query the PMP database to review their patients' utilization reports prior to issuing a prescription for a controlled substance, and by failing to review their own prescriber activity on a semi-annual basis, Respondents violated NRS 453.164(7) and NRS 639.23507.

41. Furthermore, by failing to query the PMP database to review their patients' utilization report prior to issuing a prescription for a controlled substance, and by failing to review their own prescriber activity on a semi-annual basis, each Respondent performed his or her duties as the holder of a certificate issued by the Board in an incompetent, unskillful or negligent manner.

42. As alleged above, each Respondent's conduct constitutes unprofessional conduct for which the Board may impose administrative discipline. NRS 639.210(4); NAC 639.945(1)(i).

COUNT SEVEN
Unprofessional Conduct – Prescribing Without Bona Fide Therapeutic Relationship (Respondent Bernardi)

43. As alleged above, during the course of Bernardi's employment with Young4Life, a physician's assistant evaluated patients either in-person or via telehealth, and Bernardi reviewed and signed off on patient charts and prescriptions sent under his name.

44. By failing to personally evaluate patients for whom he prescribed controlled substances, Bernardi did not form a bona fide therapeutic relationship as defined in NAC 639.752(4).

45. By permitting the use of his credentials to issue electronic prescriptions for controlled substances to patients with whom he did not have a bona fide therapeutic relationship, Respondent Bernardi engaged in unprofessional conduct and conduct contrary to the public

interest as defined in NAC 639.945(1)(n)(2), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT EIGHT
Violations of Federal and State Law – Recordkeeping
(Respondents Bernardi and Hubbard)

46. As alleged above, by failing to respond to a Board investigator's requests for information and records related to an investigation into their prescribing activities, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.090, NRS 454.286(2), NRS 453.246, NRS 639.239, 21 U.S.C. § 827, 21 CFR § 1311.120(28), 21 CFR § 1304.06, 21 CFR § 1311.305, and 21 CFR § 1311.305, and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11) and/or (12).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of each of the Respondents herein.

DATED this 28th day of AUGUST 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **Mikayla Strief, APRN** **Certificate of Registration No. CS37751,** **JUSTIN SPANGLER, PA** **Certificate of Registration No. CS28770,** **DANIEL INGLISH, DO** **Certificate of Registration No. CS22888,** **Mary Miller-Wilson, APRN** **Certificate of Registration No. CS33703,** **MARK BERNARDI, MD** **Certificate of Registration No. CS29595, and** **TIANA HUBBARD, APRN** **Certificate of Registration No. CS25791,** **Respondents.**	**Case Nos. 24-482-CS-A-S** **24-482-CS-B-S** **24-482-CS-C-S** **24-482-CS-D-S** **24-482-CS-E-S** **24-482-CS-F-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the

Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 28th day of AUGUST 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JUSTIN SPANGLER, PA** **Certificate of Registration No. CS28770,** **Respondent.**	**Case No. 24-482-CS-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

JUSTIN SPANGLER, PA

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of August 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Justin Spangler, PA
c/o JS Consulting
[redacted]
Henderson, NV [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

5S

FILED
AUG 28 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

MIKAYLA STRIEF, APRN
Certificate of Registration No. CS37751,

JUSTIN SPANGLER, PA
Certificate of Registration No. CS28770,

DANIEL INGLISH, DO
Certificate of Registration No. CS22888,

MARY MILLER-WILSON, APRN
Certificate of Registration No. CS33703,

MARK BERNARDI, MD
Certificate of Registration No. CS29595, and

TIANA HUBBARD, APRN
Certificate of Registration No. CS25791,

Respondents.

Case Nos. 24-482-CS-A-S
24-482-CS-B-S
24-482-CS-C-S
24-482-CS-D-S
24-482-CS-E-S
24-482-CS-F-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter and these respondents because, at the time of the events alleged herein, Justin Spangler, PA ("Spangler") held a registration issued by the Board, Certificate of Registration No. CS28770; Mikayla Strief, APRN ("Strief") held a registration issued by the Board, Certificate of Registration No. CS37751; Daniel Inglish, DO ("Inglish") held a registration issued by the

Board, Certificate of Registration No. CS22888; Mary Miller-Wilson, APRN ("Miller-Wilson") held a registration issued by the Board, Certificate of Registration No. CS33703; Mark Bernardi, MD ("Bernardi") held a registration issued by the Board, Certificate of Registration No. CS29595; and Tiana Hubbard, APRN ("Hubbard") held a registration issued by the Board, Certificate of Registration No. CS25791.

FACTUAL ALLEGATIONS

2. Respondent Spangler is licensed by the Nevada State Board of Medical Examiners as a physician assistant. At the time of the violations alleged herein, Spangler was a "practitioner" as that term is defined at NRS 453.126(5) and 639.0125(4).

3. Respondents Strief, Miller-Wilson, and Hubbard are licensed by the Nevada State Board of Nursing as advanced practice registered nurses. At the time of the violations alleged herein, Strief, Miller-Wilson, and Hubbard were "practitioners" as that term is defined at NRS 453.126(2) and 639.0125(3).

4. Respondent Inglish is licensed by the Nevada State Board of Osteopathic Medicine as an osteopathic physician. At the time of the violations alleged herein, Inglish was a "practitioner" as that term is defined at NRS 453.126(1) and 639.0125(1).

5. Respondent Bernardi is licensed by the Nevada State Board of Medical Examiners as a physician. At the time of the violations alleged herein, Bernardi was a "practitioner" as that term is defined at NRS 453.126(1) and 639.0125(1).

6. On or about March 2022, David Lindberg ("Lindberg") began operating the wellness clinic D.C.L., LLC, dba Magnus Medical Health and Wellness ("Magnus"), located at 8540 S. Eastern Avenue, Suite 160, in Las Vegas, Nevada. Lindberg is not a licensed practitioner as that term is defined at NRS 453.126(1) and 639.0125(1) and not licensed by the Board or the

Federal Drug Enforcement Administration ("DEA") to possess, administer, prescribe or dispense dangerous drugs or controlled substances.

7. During the relevant timeframe, Respondents Spangler, Strief, Miller-Wilson, Inglish, and Hubbard worked as practitioners at Magnus.

8. On or about September 2024, Lindberg sold Magnus to new owners Donald Min ("Min") and Young Kim ("Kim"), who renamed the business Young4Life. Neither Min nor Kim are licensed practitioners as that term is defined at NRS 453.126(1) and 639.0125(1) or licensed by the Board or DEA to possess, administer, prescribe or dispense dangerous drugs or controlled substances.

9. Min and Kim formed Young4Life in late 2024 and assumed Magnus's established customers and business model. Young4Life retained Lindberg as a marketing consultant.

10. During the relevant timeframe, Respondents Spangler and Bernardi worked as practitioners at Young4Life.

11. A Board investigation found that, as owner of Magnus, between September 2022 and September 2024, Lindberg regularly used several Magnus employees' prescribing credentials to issue prescriptions and access prescribing systems. From September 2024 through at least May 2025, as marketing consultant, Lindberg continued using Young4Life employee's prescribing credentials to issue prescriptions and access prescribing systems.

12. Specifically, during the relevant timeframe, each Respondent permitted Lindberg to access prescribing systems and issue the following controlled substance prescriptions using their electronic prescribing credentials:

A. According to Board records, between May 2024 and November 2024, while employed by Magnus and Young4Life, Spangler authorized 548 controlled

substance prescriptions for 397 unique patients. Furthermore, according to the Board's records, Spangler did not access the PMP database to review his own prescribing activity ("MyRx report") from September 2019 to July 18, 2025. Spangler has only run one patient PMP query, in October 2019.

B. Between May 2024 and November 2024, while employed by Magnus, Strief authorized 170 controlled substance prescriptions for Nevada patients. Strief checked her MyRx report only one time, in December 2024. Strief also did not run any patient PMP queries prior to December 2024.

C. Per company policy, Strief delegated the entire prescribing process to Magnus. As such, Strief sent her prescribing token to Magnus and did not personally authorize any prescriptions for armodafinil, chorionic gonad or ketamine that appeared on her prescribing report from April to November 2024.

D. Between May 2024 and May 2025, while employed by Magnus, Inglish prescribed 63 controlled substances for Nevada patients. Inglish checked his MyRx report two times, in April 2025 and August 2025. He did not check it prior to that date. Inglish has not run any patient PMP queries since June 2022.

E. Between March 2022 and March 2024, while employed by Magnus, Miller-Wilson prescribed 1,846 controlled substances for 714 unique Nevada patients. Miller-Wilson checked her MyRx report once in October 2023. She has been compliant in checking her MyRx report since October 2024.

F. Per company policy, Miller-Wilson delegated the entire prescribing process to Magnus.

G. Between February 2025 and June 25, 2025, while employed by Young4Life, Bernardi prescribed 327 controlled substances for 203 unique Nevada patients. Bernardi has not checked his MyRx report from June 2022 and July 2025. Bernardi did not run any patient PMP queries prior to August 4, 2025.

H. Per company policy at Young4Life, Spangler or another physician's assistant would evaluate patients, generally via telehealth. Bernardi would then sign off on patient charts and prescriptions that were sent via his electronic credentials. Bernardi delegated the issuing of electronic prescriptions to someone else at Young4Life.

I. Between February 2023 and March 2024, while employed by Magnus, Hubbard prescribed 381 controlled substances for 202 unique Nevada patients. Hubbard checked her MyRx report only one time, in October 2024. She has not run any patient PMP queries between April 2019 and May 2025.

13. Between June 30, 2025 through August 20, 2025, Board Investigator Dena McClish (McClish) attempted to communicate with Bernardi to discuss his patient records and employment at Young4Life. Although Bernardi indicated that he would cooperate with McClish's investigation, he ultimately failed to respond to her requests for information.

14. On or about July 1, 2025, McClish attempted to contact Hubbard through certified and regular U.S. Mail and e-mail about her patient records and employment with Magnus. Hubbard failed to respond to her requests for information.

\\\

\\\

\\\

PRIOR DISCIPLINE

15. On December 3, 2025, the Board disciplined Respondent Inglish for allowing unlicensed individuals independent access to dangerous drugs; allowing unlicensed individuals to access, possess, furnish, and administer dangerous drugs; permitting the administration of patient-specific prescription medications to multiple patients; intermingling of adulterated and expired drugs; falsifying prescriptions; and aiding and abetting unlicensed practice. The Board placed Respondent Inglish on one-year probation beginning on December 3, 2025, and ordered him to pay a $5,000 fine and $1,000 in fees and costs.

APPLICABLE LAW

16. Pursuant to NRS 639.100(1), it is unlawful for any person to manufacture, engage in wholesale distribution, compound, sell or dispense, or permit to be manufactured, distributed at wholesale, compounded, sold or dispensed, any drug, poison, medicine or chemical, or to dispense or compound, or permit to be dispensed or compounded drugs without having secured the appropriate license and/or certificate of registration from the Board.

17. Falsifying a prescription for a controlled substance is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1).

18. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession, to a patient with whom the practitioner has established a bona fide therapeutic relationship. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a); 21 CFR § 1306.04(a); NRS 453.381(1); NRS 639.235(1); NRS 639.23911(1)(a); NRS 639.2813(1).

19. A practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor, or biometric information, with any other person. The practitioner must not allow any other person to use the token or enter the knowledge factor or other identification means to sign prescriptions for controlled substances. 21 CFR § 1311.102 and NAC 639.7105(2)(b).

20. The Controlled Substances Act imposes strict liability on registrants to provide effective controls and procedures to guard against theft and diversion, which includes the duty to safeguard prescribing credentials from unauthorized use. *See* 21 CFR 1301.71(a). 21 U.S.C. § 843(a)(2) criminalizes the use of another person's DEA registration number

21. A practitioner shall, before issuing an initial prescription for a controlled substance, and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the PMP. NRS 639.23507.

22. A practitioner registered with the Board to write prescriptions for controlled substances must access his or her prescriber activity in the PMP at least once every 6 months to review prescriptions issued by the practitioner and to verify for the Board that he or she continues to have access to the PMP. NRS 453.164(7).

23. Any licensee registered with the Board must provide access to all records of sale and disposition of drugs, medicines or poisons or devices or appliances that are restricted by federal law to sale by or on the order of a physician, to members of the Board, its inspectors, and investigators. NRS 639.090. *See also* NRS 639.239 (duty to provide prescription records); NRS 453.246 (records related to controlled substances).

24. Every practitioner who engages in the practicing of furnishing dangerous drugs to patients shall maintain a complete and accurate record of all dangerous drugs purchased and those sold on prescription, dispensed, furnished or disposed of otherwise. NRS 454.286(1). The records must be retained for a period of 2 years and must be open to inspection by members, inspectors or investigators of the Board. NRS 454.286(2). *See also* 21 U.S.C. § 827 (recordkeeping requirements by registrants); 21 CFR § 1304.06 and 21 CFR § 1311.305 (regarding electronic prescription records).

25. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1)(e) and NRS 639.210(4).

26. Prescribing a drug to any patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n)(2) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4). A bona fide relationship shall be deemed to exist if the patient was examined in person, electronically, telephonically or by fiber optics within or outside of this State or the United States by the practitioner within the 6 months immediately preceding the date the prescription was issued. NAC 639.752.

27. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

28. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

29. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

30. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

31. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 upon a finding that the registrant has committed an act that renders registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Unprofessional Conduct -Party to Fraudulent or Deceitful Practice or Transaction by Permitting Use of Credentials
(All Respondents)

32. As alleged above, by permitting Lindberg to use their credentials and act under their authority to fraudulently issue prescriptions for controlled substances, each Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(l)(e), NRS 453.241(1) and/or NRS 639.210(4).

\\\

\\\

COUNT TWO

Unprofessional Conduct -Incompetent, Unskillful or Negligent Performance of Duties by Allowing Prescribing Credentials to be Compromised
(All Respondents)

33. As alleged above, to the extent each Respondent's electronic prescribing credentials were compromised and resulted in the unlawful issuance of fraudulent controlled substance prescriptions by a third party, Respondents failed to comply with 21 CFR § 1311.102, NRS 453.164(7) and NAC 639.7105(2)(b), performed their duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner, and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), committed acts that render their registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(4), (11) and (12).

COUNT THREE

Violations of Federal Controlled Substances Act – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(All Respondents)

34. As alleged above, by permitting Lindberg to use their credentials and act under their authority to issue electronic prescriptions for controlled substances, each Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR 1301.71(a). 21 U.S.C. § 843(a)(2),21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 846, 21 CFR § 1306.03(a), 21 CFR § 1306.04(a), 21 CFR § 1311.100 and/or 21 CFR § 1311.102 and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1) and/or NRS 639.210(11).

\\\

\\\

\\\

COUNT FOUR

Unprofessional Conduct – Assisting or abetting unlicensed practice
(All Respondents)

35. As alleged above, Lindberg did not have licensure from the Board as required by NRS 639.100(1) when he used each Respondent's credential and acted under their authority to issue electronic prescriptions for controlled substances.

36. By assisting and abetting Lindberg's unlicensed activity, each Respondent engaged in unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(j), and is subject to discipline pursuant to NRS 639.210(4).

COUNT FIVE

Violations of State Law – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(All Respondents)

37. As alleged above, by permitting Lindberg to use their credentials and act under their authority to issue electronic prescriptions for controlled substances, each Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.381(1), NRS 453.385, NRS 453.401(l)(a), NRS 639.235(1), NRS 639.23535, NRS 639.23911(1)(a), NRS 639.2813(1) and/or NAC 639.7105, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT SIX

Unprofessional Conduct by a Practitioner – Failure to Query PMP Database
(All Respondents)

38. As alleged above, each Respondent failed to query the PMP database regarding his or her patients' histories of using controlled substances as required by law. NRS 639.23507.

39. As alleged above, each Respondent failed to query the PMP database regarding his or her own prescriber activity as required by law. NRS 453.164(7).

40. By failing to query the PMP database to review their patients' utilization reports prior to issuing a prescription for a controlled substance, and by failing to review their own prescriber activity on a semi-annual basis, Respondents violated NRS 453.164(7) and NRS 639.23507.

41. Furthermore, by failing to query the PMP database to review their patients' utilization report prior to issuing a prescription for a controlled substance, and by failing to review their own prescriber activity on a semi-annual basis, each Respondent performed his or her duties as the holder of a certificate issued by the Board in an incompetent, unskillful or negligent manner.

42. As alleged above, each Respondent's conduct constitutes unprofessional conduct for which the Board may impose administrative discipline. NRS 639.210(4); NAC 639.945(1)(i).

COUNT SEVEN
Unprofessional Conduct – Prescribing Without Bona Fide Therapeutic Relationship (Respondent Bernardi)

43. As alleged above, during the course of Bernardi's employment with Young4Life, a physician's assistant evaluated patients either in-person or via telehealth, and Bernardi reviewed and signed off on patient charts and prescriptions sent under his name.

44. By failing to personally evaluate patients for whom he prescribed controlled substances, Bernardi did not form a bona fide therapeutic relationship as defined in NAC 639.752(4).

45. By permitting the use of his credentials to issue electronic prescriptions for controlled substances to patients with whom he did not have a bona fide therapeutic relationship, Respondent Bernardi engaged in unprofessional conduct and conduct contrary to the public

interest as defined in NAC 639.945(1)(n)(2), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT EIGHT
Violations of Federal and State Law – Recordkeeping
(Respondents Bernardi and Hubbard)

46. As alleged above, by failing to respond to a Board investigator's requests for information and records related to an investigation into their prescribing activities, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.090, NRS 454.286(2), NRS 453.246, NRS 639.239, 21 U.S.C. § 827, 21 CFR § 1311.120(28), 21 CFR § 1304.06, 21 CFR § 1311.305, and 21 CFR § 1311.305, and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11) and/or (12).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of each of the Respondents herein.

DATED this 26th day of AUGUST 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **Mikayla Strief, APRN** **Certificate of Registration No. CS37751,** **JUSTIN SPANGLER, PA** **Certificate of Registration No. CS28770,** **DANIEL INGLISH, DO** **Certificate of Registration No. CS22888,** **Mary Miller-Wilson, APRN** **Certificate of Registration No. CS33703,** **MARK BERNARDI, MD** **Certificate of Registration No. CS29595, and** **TIANA HUBBARD, APRN** **Certificate of Registration No. CS25791,** **Respondents.**	**Case Nos. 24-482-CS-A-S** **24-482-CS-B-S** **24-482-CS-C-S** **24-482-CS-D-S** **24-482-CS-E-S** **24-482-CS-F-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the

Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 28th day of AUGUST 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DANIEL INGLISH, DO** **Certificate of Registration No. CS22888,** **Respondent.**	**Case No. 24-482-CS-C-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

DANIEL INGLISH, DO

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of August 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Daniel Inglish, DO
7391 W Charleston Blvd #140
Las Vegas, NV 89117

Daniel Inglish, DO
8540 S Eastern Ave., Ste. 160
Las Vegas, NV 89123

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

5T

FILED
AUG 2 8 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MIKAYLA STRIEF, APRN** **Certificate of Registration No. CS37751,** **JUSTIN SPANGLER, PA** **Certificate of Registration No. CS28770,** **DANIEL INGLISH, DO** **Certificate of Registration No. CS22888,** **MARY MILLER-WILSON, APRN** **Certificate of Registration No. CS33703,** **MARK BERNARDI, MD** **Certificate of Registration No. CS29595, and** **TIANA HUBBARD, APRN** **Certificate of Registration No. CS25791,** **Respondents.**	**Case Nos. 24-482-CS-A-S** **24-482-CS-B-S** **24-482-CS-C-S** **24-482-CS-D-S** **24-482-CS-E-S** **24-482-CS-F-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter and these respondents because, at the time of the events alleged herein, Justin Spangler, PA ("Spangler") held a registration issued by the Board, Certificate of Registration No. CS28770; Mikayla Strief, APRN ("Strief") held a registration issued by the Board, Certificate of Registration No. CS37751; Daniel Inglish, DO ("Inglish") held a registration issued by the

Board, Certificate of Registration No. CS22888; Mary Miller-Wilson, APRN ("Miller-Wilson") held a registration issued by the Board, Certificate of Registration No. CS33703; Mark Bernardi, MD ("Bernardi") held a registration issued by the Board, Certificate of Registration No. CS29595; and Tiana Hubbard, APRN ("Hubbard") held a registration issued by the Board, Certificate of Registration No. CS25791.

FACTUAL ALLEGATIONS

2. Respondent Spangler is licensed by the Nevada State Board of Medical Examiners as a physician assistant. At the time of the violations alleged herein, Spangler was a "practitioner" as that term is defined at NRS 453.126(5) and 639.0125(4).

3. Respondents Strief, Miller-Wilson, and Hubbard are licensed by the Nevada State Board of Nursing as advanced practice registered nurses. At the time of the violations alleged herein, Strief, Miller-Wilson, and Hubbard were "practitioners" as that term is defined at NRS 453.126(2) and 639.0125(3).

4. Respondent Inglish is licensed by the Nevada State Board of Osteopathic Medicine as an osteopathic physician. At the time of the violations alleged herein, Inglish was a "practitioner" as that term is defined at NRS 453.126(1) and 639.0125(1).

5. Respondent Bernardi is licensed by the Nevada State Board of Medical Examiners as a physician. At the time of the violations alleged herein, Bernardi was a "practitioner" as that term is defined at NRS 453.126(1) and 639.0125(1).

6. On or about March 2022, David Lindberg ("Lindberg") began operating the wellness clinic D.C.L., LLC, dba Magnus Medical Health and Wellness ("Magnus"), located at 8540 S. Eastern Avenue, Suite 160, in Las Vegas, Nevada. Lindberg is not a licensed practitioner as that term is defined at NRS 453.126(1) and 639.0125(1) and not licensed by the Board or the

Federal Drug Enforcement Administration ("DEA") to possess, administer, prescribe or dispense dangerous drugs or controlled substances.

7. During the relevant timeframe, Respondents Spangler, Strief, Miller-Wilson, Inglish, and Hubbard worked as practitioners at Magnus.

8. On or about September 2024, Lindberg sold Magnus to new owners Donald Min ("Min") and Young Kim ("Kim"), who renamed the business Young4Life. Neither Min nor Kim are licensed practitioners as that term is defined at NRS 453.126(1) and 639.0125(1) or licensed by the Board or DEA to possess, administer, prescribe or dispense dangerous drugs or controlled substances.

9. Min and Kim formed Young4Life in late 2024 and assumed Magnus's established customers and business model. Young4Life retained Lindberg as a marketing consultant.

10. During the relevant timeframe, Respondents Spangler and Bernardi worked as practitioners at Young4Life.

11. A Board investigation found that, as owner of Magnus, between September 2022 and September 2024, Lindberg regularly used several Magnus employees' prescribing credentials to issue prescriptions and access prescribing systems. From September 2024 through at least May 2025, as marketing consultant, Lindberg continued using Young4Life employee's prescribing credentials to issue prescriptions and access prescribing systems.

12. Specifically, during the relevant timeframe, each Respondent permitted Lindberg to access prescribing systems and issue the following controlled substance prescriptions using their electronic prescribing credentials:

A. According to Board records, between May 2024 and November 2024, while employed by Magnus and Young4Life, Spangler authorized 548 controlled

substance prescriptions for 397 unique patients. Furthermore, according to the Board's records, Spangler did not access the PMP database to review his own prescribing activity ("MyRx report") from September 2019 to July 18, 2025. Spangler has only run one patient PMP query, in October 2019.

B. Between May 2024 and November 2024, while employed by Magnus, Strief authorized 170 controlled substance prescriptions for Nevada patients. Strief checked her MyRx report only one time, in December 2024. Strief also did not run any patient PMP queries prior to December 2024.

C. Per company policy, Strief delegated the entire prescribing process to Magnus. As such, Strief sent her prescribing token to Magnus and did not personally authorize any prescriptions for armodafinil, chorionic gonad or ketamine that appeared on her prescribing report from April to November 2024.

D. Between May 2024 and May 2025, while employed by Magnus, Inglish prescribed 63 controlled substances for Nevada patients. Inglish checked his MyRx report two times, in April 2025 and August 2025. He did not check it prior to that date. Inglish has not run any patient PMP queries since June 2022.

E. Between March 2022 and March 2024, while employed by Magnus, Miller-Wilson prescribed 1,846 controlled substances for 714 unique Nevada patients. Miller-Wilson checked her MyRx report once in October 2023. She has been compliant in checking her MyRx report since October 2024.

F. Per company policy, Miller-Wilson delegated the entire prescribing process to Magnus.

G. Between February 2025 and June 25, 2025, while employed by Young4Life, Bernardi prescribed 327 controlled substances for 203 unique Nevada patients. Bernardi has not checked his MyRx report from June 2022 and July 2025. Bernardi did not run any patient PMP queries prior to August 4, 2025.

H. Per company policy at Young4Life, Spangler or another physician's assistant would evaluate patients, generally via telehealth. Bernardi would then sign off on patient charts and prescriptions that were sent via his electronic credentials. Bernardi delegated the issuing of electronic prescriptions to someone else at Young4Life.

I. Between February 2023 and March 2024, while employed by Magnus, Hubbard prescribed 381 controlled substances for 202 unique Nevada patients. Hubbard checked her MyRx report only one time, in October 2024. She has not run any patient PMP queries between April 2019 and May 2025.

13. Between June 30, 2025 through August 20, 2025, Board Investigator Dena McClish (McClish) attempted to communicate with Bernardi to discuss his patient records and employment at Young4Life. Although Bernardi indicated that he would cooperate with McClish's investigation, he ultimately failed to respond to her requests for information.

14. On or about July 1, 2025, McClish attempted to contact Hubbard through certified and regular U.S. Mail and e-mail about her patient records and employment with Magnus. Hubbard failed to respond to her requests for information.

\\\

\\\

\\\

PRIOR DISCIPLINE

15. On December 3, 2025, the Board disciplined Respondent Inglish for allowing unlicensed individuals independent access to dangerous drugs; allowing unlicensed individuals to access, possess, furnish, and administer dangerous drugs; permitting the administration of patient-specific prescription medications to multiple patients; intermingling of adulterated and expired drugs; falsifying prescriptions; and aiding and abetting unlicensed practice. The Board placed Respondent Inglish on one-year probation beginning on December 3, 2025, and ordered him to pay a $5,000 fine and $1,000 in fees and costs.

APPLICABLE LAW

16. Pursuant to NRS 639.100(1), it is unlawful for any person to manufacture, engage in wholesale distribution, compound, sell or dispense, or permit to be manufactured, distributed at wholesale, compounded, sold or dispensed, any drug, poison, medicine or chemical, or to dispense or compound, or permit to be dispensed or compounded drugs without having secured the appropriate license and/or certificate of registration from the Board.

17. Falsifying a prescription for a controlled substance is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1).

18. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession, to a patient with whom the practitioner has established a bona fide therapeutic relationship. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a); 21 CFR § 1306.04(a); NRS 453.381(1); NRS 639.235(1); NRS 639.23911(1)(a); NRS 639.2813(1).

19. A practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor, or biometric information, with any other person. The practitioner must not allow any other person to use the token or enter the knowledge factor or other identification means to sign prescriptions for controlled substances. 21 CFR § 1311.102 and NAC 639.7105(2)(b).

20. The Controlled Substances Act imposes strict liability on registrants to provide effective controls and procedures to guard against theft and diversion, which includes the duty to safeguard prescribing credentials from unauthorized use. *See* 21 CFR 1301.71(a). 21 U.S.C. § 843(a)(2) criminalizes the use of another person's DEA registration number

21. A practitioner shall, before issuing an initial prescription for a controlled substance, and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the PMP. NRS 639.23507.

22. A practitioner registered with the Board to write prescriptions for controlled substances must access his or her prescriber activity in the PMP at least once every 6 months to review prescriptions issued by the practitioner and to verify for the Board that he or she continues to have access to the PMP. NRS 453.164(7).

23. Any licensee registered with the Board must provide access to all records of sale and disposition of drugs, medicines or poisons or devices or appliances that are restricted by federal law to sale by or on the order of a physician, to members of the Board, its inspectors, and investigators. NRS 639.090. *See also* NRS 639.239 (duty to provide prescription records); NRS 453.246 (records related to controlled substances).

24. Every practitioner who engages in the practicing of furnishing dangerous drugs to patients shall maintain a complete and accurate record of all dangerous drugs purchased and those sold on prescription, dispensed, furnished or disposed of otherwise. NRS 454.286(1). The records must be retained for a period of 2 years and must be open to inspection by members, inspectors or investigators of the Board. NRS 454.286(2). *See also* 21 U.S.C. § 827 (recordkeeping requirements by registrants); 21 CFR § 1304.06 and 21 CFR § 1311.305 (regarding electronic prescription records).

25. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1)(e) and NRS 639.210(4).

26. Prescribing a drug to any patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n)(2) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4). A bona fide relationship shall be deemed to exist if the patient was examined in person, electronically, telephonically or by fiber optics within or outside of this State or the United States by the practitioner within the 6 months immediately preceding the date the prescription was issued. NAC 639.752.

27. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

28. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

29. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

30. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

31. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 upon a finding that the registrant has committed an act that renders registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE
Unprofessional Conduct -Party to Fraudulent or Deceitful Practice or Transaction by Permitting Use of Credentials
(All Respondents)

32. As alleged above, by permitting Lindberg to use their credentials and act under their authority to fraudulently issue prescriptions for controlled substances, each Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(l)(e), NRS 453.241(1) and/or NRS 639.210(4).

\\\

\\\

COUNT TWO

Unprofessional Conduct -Incompetent, Unskillful or Negligent Performance of Duties by Allowing Prescribing Credentials to be Compromised
(All Respondents)

33. As alleged above, to the extent each Respondent's electronic prescribing credentials were compromised and resulted in the unlawful issuance of fraudulent controlled substance prescriptions by a third party, Respondents failed to comply with 21 CFR § 1311.102, NRS 453.164(7) and NAC 639.7105(2)(b), performed their duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner, and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), committed acts that render their registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(4), (11) and (12).

COUNT THREE

Violations of Federal Controlled Substances Act – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(All Respondents)

34. As alleged above, by permitting Lindberg to use their credentials and act under their authority to issue electronic prescriptions for controlled substances, each Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR 1301.71(a). 21 U.S.C. § 843(a)(2),21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 846, 21 CFR § 1306.03(a), 21 CFR § 1306.04(a), 21 CFR § 1311.100 and/or 21 CFR § 1311.102 and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1) and/or NRS 639.210(11).

\\\

\\\

\\\

COUNT FOUR
Unprofessional Conduct – Assisting or abetting unlicensed practice
(All Respondents)

35. As alleged above, Lindberg did not have licensure from the Board as required by NRS 639.100(1) when he used each Respondent's credential and acted under their authority to issue electronic prescriptions for controlled substances.

36. By assisting and abetting Lindberg's unlicensed activity, each Respondent engaged in unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(j), and is subject to discipline pursuant to NRS 639.210(4).

COUNT FIVE
Violations of State Law – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(All Respondents)

37. As alleged above, by permitting Lindberg to use their credentials and act under their authority to issue electronic prescriptions for controlled substances, each Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.381(1), NRS 453.385, NRS 453.401(l)(a), NRS 639.235(1), NRS 639.23535, NRS 639.23911(1)(a), NRS 639.2813(1) and/or NAC 639.7105, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT SIX
Unprofessional Conduct by a Practitioner – Failure to Query PMP Database
(All Respondents)

38. As alleged above, each Respondent failed to query the PMP database regarding his or her patients' histories of using controlled substances as required by law. NRS 639.23507.

39. As alleged above, each Respondent failed to query the PMP database regarding his or her own prescriber activity as required by law. NRS 453.164(7).

40. By failing to query the PMP database to review their patients' utilization reports prior to issuing a prescription for a controlled substance, and by failing to review their own prescriber activity on a semi-annual basis, Respondents violated NRS 453.164(7) and NRS 639.23507.

41. Furthermore, by failing to query the PMP database to review their patients' utilization report prior to issuing a prescription for a controlled substance, and by failing to review their own prescriber activity on a semi-annual basis, each Respondent performed his or her duties as the holder of a certificate issued by the Board in an incompetent, unskillful or negligent manner.

42. As alleged above, each Respondent's conduct constitutes unprofessional conduct for which the Board may impose administrative discipline. NRS 639.210(4); NAC 639.945(1)(i).

COUNT SEVEN
Unprofessional Conduct – Prescribing Without Bona Fide Therapeutic Relationship
(Respondent Bernardi)

43. As alleged above, during the course of Bernardi's employment with Young4Life, a physician's assistant evaluated patients either in-person or via telehealth, and Bernardi reviewed and signed off on patient charts and prescriptions sent under his name.

44. By failing to personally evaluate patients for whom he prescribed controlled substances, Bernardi did not form a bona fide therapeutic relationship as defined in NAC 639.752(4).

45. By permitting the use of his credentials to issue electronic prescriptions for controlled substances to patients with whom he did not have a bona fide therapeutic relationship, Respondent Bernardi engaged in unprofessional conduct and conduct contrary to the public

interest as defined in NAC 639.945(1)(n)(2), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT EIGHT
Violations of Federal and State Law – Recordkeeping
(Respondents Bernardi and Hubbard)

46. As alleged above, by failing to respond to a Board investigator's requests for information and records related to an investigation into their prescribing activities, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.090, NRS 454.286(2), NRS 453.246, NRS 639.239, 21 U.S.C. § 827, 21 CFR § 1311.120(28), 21 CFR § 1304.06, 21 CFR § 1311.305, and 21 CFR § 1311.305, and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11) and/or (12).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of each of the Respondents herein.

DATED this 26th day of AUGUST 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **Mikayla Strief, APRN** **Certificate of Registration No. CS37751,** **JUSTIN SPANGLER, PA** **Certificate of Registration No. CS28770,** **DANIEL INGLISH, DO** **Certificate of Registration No. CS22888,** **Mary Miller-Wilson, APRN** **Certificate of Registration No. CS33703,** **MARK BERNARDI, MD** **Certificate of Registration No. CS29595, and** **TIANA HUBBARD, APRN** **Certificate of Registration No. CS25791,** **Respondents.**	**Case Nos. 24-482-CS-A-S** **24-482-CS-B-S** **24-482-CS-C-S** **24-482-CS-D-S** **24-482-CS-E-S** **24-482-CS-F-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the

Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of AUGUST 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARY MILLER-WILSON, APRN** **Certificate of Registration No. CS33703,** **Respondent.**	**Case No. 24-482-CS-D-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

MARY MILLER-WILSON, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of August 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Mary Miller-Wilson, APRN
10120 S Eastern Ave., Suite 245
Las Vegas, NV 89052

Mary Miller-Wilson, APRN
[redacted]
Bloomfield Hills, MI [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

5U

FILED
AUG 2 8 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

MIKAYLA STRIEF, APRN
Certificate of Registration No. CS37751,

JUSTIN SPANGLER, PA
Certificate of Registration No. CS28770,

DANIEL INGLISH, DO
Certificate of Registration No. CS22888,

MARY MILLER-WILSON, APRN
Certificate of Registration No. CS33703,

MARK BERNARDI, MD
Certificate of Registration No. CS29595, and

TIANA HUBBARD, APRN
Certificate of Registration No. CS25791,

Respondents.

Case Nos. 24-482-CS-A-S
24-482-CS-B-S
24-482-CS-C-S
24-482-CS-D-S
24-482-CS-E-S
24-482-CS-F-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter and these respondents because, at the time of the events alleged herein, Justin Spangler, PA ("Spangler") held a registration issued by the Board, Certificate of Registration No. CS28770; Mikayla Strief, APRN ("Strief") held a registration issued by the Board, Certificate of Registration No. CS37751; Daniel Inglish, DO ("Inglish") held a registration issued by the

Board, Certificate of Registration No. CS22888; Mary Miller-Wilson, APRN ("Miller-Wilson") held a registration issued by the Board, Certificate of Registration No. CS33703; Mark Bernardi, MD ("Bernardi") held a registration issued by the Board, Certificate of Registration No. CS29595; and Tiana Hubbard, APRN ("Hubbard") held a registration issued by the Board, Certificate of Registration No. CS25791.

FACTUAL ALLEGATIONS

2. Respondent Spangler is licensed by the Nevada State Board of Medical Examiners as a physician assistant. At the time of the violations alleged herein, Spangler was a "practitioner" as that term is defined at NRS 453.126(5) and 639.0125(4).

3. Respondents Strief, Miller-Wilson, and Hubbard are licensed by the Nevada State Board of Nursing as advanced practice registered nurses. At the time of the violations alleged herein, Strief, Miller-Wilson, and Hubbard were "practitioners" as that term is defined at NRS 453.126(2) and 639.0125(3).

4. Respondent Inglish is licensed by the Nevada State Board of Osteopathic Medicine as an osteopathic physician. At the time of the violations alleged herein, Inglish was a "practitioner" as that term is defined at NRS 453.126(1) and 639.0125(1).

5. Respondent Bernardi is licensed by the Nevada State Board of Medical Examiners as a physician. At the time of the violations alleged herein, Bernardi was a "practitioner" as that term is defined at NRS 453.126(1) and 639.0125(1).

6. On or about March 2022, David Lindberg ("Lindberg") began operating the wellness clinic D.C.L., LLC, dba Magnus Medical Health and Wellness ("Magnus"), located at 8540 S. Eastern Avenue, Suite 160, in Las Vegas, Nevada. Lindberg is not a licensed practitioner as that term is defined at NRS 453.126(1) and 639.0125(1) and not licensed by the Board or the

Federal Drug Enforcement Administration ("DEA") to possess, administer, prescribe or dispense dangerous drugs or controlled substances.

7. During the relevant timeframe, Respondents Spangler, Strief, Miller-Wilson, Inglish, and Hubbard worked as practitioners at Magnus.

8. On or about September 2024, Lindberg sold Magnus to new owners Donald Min ("Min") and Young Kim ("Kim"), who renamed the business Young4Life. Neither Min nor Kim are licensed practitioners as that term is defined at NRS 453.126(1) and 639.0125(1) or licensed by the Board or DEA to possess, administer, prescribe or dispense dangerous drugs or controlled substances.

9. Min and Kim formed Young4Life in late 2024 and assumed Magnus's established customers and business model. Young4Life retained Lindberg as a marketing consultant.

10. During the relevant timeframe, Respondents Spangler and Bernardi worked as practitioners at Young4Life.

11. A Board investigation found that, as owner of Magnus, between September 2022 and September 2024, Lindberg regularly used several Magnus employees' prescribing credentials to issue prescriptions and access prescribing systems. From September 2024 through at least May 2025, as marketing consultant, Lindberg continued using Young4Life employee's prescribing credentials to issue prescriptions and access prescribing systems.

12. Specifically, during the relevant timeframe, each Respondent permitted Lindberg to access prescribing systems and issue the following controlled substance prescriptions using their electronic prescribing credentials:

A. According to Board records, between May 2024 and November 2024, while employed by Magnus and Young4Life, Spangler authorized 548 controlled

substance prescriptions for 397 unique patients. Furthermore, according to the Board's records, Spangler did not access the PMP database to review his own prescribing activity ("MyRx report") from September 2019 to July 18, 2025. Spangler has only run one patient PMP query, in October 2019.

B. Between May 2024 and November 2024, while employed by Magnus, Strief authorized 170 controlled substance prescriptions for Nevada patients. Strief checked her MyRx report only one time, in December 2024. Strief also did not run any patient PMP queries prior to December 2024.

C. Per company policy, Strief delegated the entire prescribing process to Magnus. As such, Strief sent her prescribing token to Magnus and did not personally authorize any prescriptions for armodafinil, chorionic gonad or ketamine that appeared on her prescribing report from April to November 2024.

D. Between May 2024 and May 2025, while employed by Magnus, Inglish prescribed 63 controlled substances for Nevada patients. Inglish checked his MyRx report two times, in April 2025 and August 2025. He did not check it prior to that date. Inglish has not run any patient PMP queries since June 2022.

E. Between March 2022 and March 2024, while employed by Magnus, Miller-Wilson prescribed 1,846 controlled substances for 714 unique Nevada patients. Miller-Wilson checked her MyRx report once in October 2023. She has been compliant in checking her MyRx report since October 2024.

F. Per company policy, Miller-Wilson delegated the entire prescribing process to Magnus.

G. Between February 2025 and June 25, 2025, while employed by Young4Life, Bernardi prescribed 327 controlled substances for 203 unique Nevada patients. Bernardi has not checked his MyRx report from June 2022 and July 2025. Bernardi did not run any patient PMP queries prior to August 4, 2025.

H. Per company policy at Young4Life, Spangler or another physician's assistant would evaluate patients, generally via telehealth. Bernardi would then sign off on patient charts and prescriptions that were sent via his electronic credentials. Bernardi delegated the issuing of electronic prescriptions to someone else at Young4Life.

I. Between February 2023 and March 2024, while employed by Magnus, Hubbard prescribed 381 controlled substances for 202 unique Nevada patients. Hubbard checked her MyRx report only one time, in October 2024. She has not run any patient PMP queries between April 2019 and May 2025.

13. Between June 30, 2025 through August 20, 2025, Board Investigator Dena McClish (McClish) attempted to communicate with Bernardi to discuss his patient records and employment at Young4Life. Although Bernardi indicated that he would cooperate with McClish's investigation, he ultimately failed to respond to her requests for information.

14. On or about July 1, 2025, McClish attempted to contact Hubbard through certified and regular U.S. Mail and e-mail about her patient records and employment with Magnus. Hubbard failed to respond to her requests for information.

\\\

\\\

\\\

PRIOR DISCIPLINE

15. On December 3, 2025, the Board disciplined Respondent Inglish for allowing unlicensed individuals independent access to dangerous drugs; allowing unlicensed individuals to access, possess, furnish, and administer dangerous drugs; permitting the administration of patient-specific prescription medications to multiple patients; intermingling of adulterated and expired drugs; falsifying prescriptions; and aiding and abetting unlicensed practice. The Board placed Respondent Inglish on one-year probation beginning on December 3, 2025, and ordered him to pay a $5,000 fine and $1,000 in fees and costs.

APPLICABLE LAW

16. Pursuant to NRS 639.100(1), it is unlawful for any person to manufacture, engage in wholesale distribution, compound, sell or dispense, or permit to be manufactured, distributed at wholesale, compounded, sold or dispensed, any drug, poison, medicine or chemical, or to dispense or compound, or permit to be dispensed or compounded drugs without having secured the appropriate license and/or certificate of registration from the Board.

17. Falsifying a prescription for a controlled substance is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1).

18. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession, to a patient with whom the practitioner has established a bona fide therapeutic relationship. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a); 21 CFR § 1306.04(a); NRS 453.381(1); NRS 639.235(1); NRS 639.23911(1)(a); NRS 639.2813(1).

19. A practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor, or biometric information, with any other person. The practitioner must not allow any other person to use the token or enter the knowledge factor or other identification means to sign prescriptions for controlled substances. 21 CFR § 1311.102 and NAC 639.7105(2)(b).

20. The Controlled Substances Act imposes strict liability on registrants to provide effective controls and procedures to guard against theft and diversion, which includes the duty to safeguard prescribing credentials from unauthorized use. *See* 21 CFR 1301.71(a). 21 U.S.C. § 843(a)(2) criminalizes the use of another person's DEA registration number

21. A practitioner shall, before issuing an initial prescription for a controlled substance, and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the PMP. NRS 639.23507.

22. A practitioner registered with the Board to write prescriptions for controlled substances must access his or her prescriber activity in the PMP at least once every 6 months to review prescriptions issued by the practitioner and to verify for the Board that he or she continues to have access to the PMP. NRS 453.164(7).

23. Any licensee registered with the Board must provide access to all records of sale and disposition of drugs, medicines or poisons or devices or appliances that are restricted by federal law to sale by or on the order of a physician, to members of the Board, its inspectors, and investigators. NRS 639.090. *See also* NRS 639.239 (duty to provide prescription records); NRS 453.246 (records related to controlled substances).

24. Every practitioner who engages in the practicing of furnishing dangerous drugs to patients shall maintain a complete and accurate record of all dangerous drugs purchased and those sold on prescription, dispensed, furnished or disposed of otherwise. NRS 454.286(1). The records must be retained for a period of 2 years and must be open to inspection by members, inspectors or investigators of the Board. NRS 454.286(2). *See also* 21 U.S.C. § 827 (recordkeeping requirements by registrants); 21 CFR § 1304.06 and 21 CFR § 1311.305 (regarding electronic prescription records).

25. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1)(e) and NRS 639.210(4).

26. Prescribing a drug to any patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n)(2) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4). A bona fide relationship shall be deemed to exist if the patient was examined in person, electronically, telephonically or by fiber optics within or outside of this State or the United States by the practitioner within the 6 months immediately preceding the date the prescription was issued. NAC 639.752.

27. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

28. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

29. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

30. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

31. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 upon a finding that the registrant has committed an act that renders registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Unprofessional Conduct -Party to Fraudulent or Deceitful Practice or Transaction by Permitting Use of Credentials
(All Respondents)

32. As alleged above, by permitting Lindberg to use their credentials and act under their authority to fraudulently issue prescriptions for controlled substances, each Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(l)(e), NRS 453.241(1) and/or NRS 639.210(4).

\\\

\\\

COUNT TWO

Unprofessional Conduct -Incompetent, Unskillful or Negligent Performance of Duties by Allowing Prescribing Credentials to be Compromised
(All Respondents)

33. As alleged above, to the extent each Respondent's electronic prescribing credentials were compromised and resulted in the unlawful issuance of fraudulent controlled substance prescriptions by a third party, Respondents failed to comply with 21 CFR § 1311.102, NRS 453.164(7) and NAC 639.7105(2)(b), performed their duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner, and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), committed acts that render their registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(4), (11) and (12).

COUNT THREE

Violations of Federal Controlled Substances Act – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(All Respondents)

34. As alleged above, by permitting Lindberg to use their credentials and act under their authority to issue electronic prescriptions for controlled substances, each Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR 1301.71(a). 21 U.S.C. § 843(a)(2),21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 846, 21 CFR § 1306.03(a), 21 CFR § 1306.04(a), 21 CFR § 1311.100 and/or 21 CFR § 1311.102 and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1) and/or NRS 639.210(11).

\\\

\\\

\\\

COUNT FOUR

Unprofessional Conduct – Assisting or abetting unlicensed practice
(All Respondents)

35. As alleged above, Lindberg did not have licensure from the Board as required by NRS 639.100(1) when he used each Respondent's credential and acted under their authority to issue electronic prescriptions for controlled substances.

36. By assisting and abetting Lindberg's unlicensed activity, each Respondent engaged in unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(j), and is subject to discipline pursuant to NRS 639.210(4).

COUNT FIVE

Violations of State Law – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(All Respondents)

37. As alleged above, by permitting Lindberg to use their credentials and act under their authority to issue electronic prescriptions for controlled substances, each Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.381(1), NRS 453.385, NRS 453.401(l)(a), NRS 639.235(1), NRS 639.23535, NRS 639.23911(1)(a), NRS 639.2813(1) and/or NAC 639.7105, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT SIX

Unprofessional Conduct by a Practitioner – Failure to Query PMP Database
(All Respondents)

38. As alleged above, each Respondent failed to query the PMP database regarding his or her patients' histories of using controlled substances as required by law. NRS 639.23507.

39. As alleged above, each Respondent failed to query the PMP database regarding his or her own prescriber activity as required by law. NRS 453.164(7).

40. By failing to query the PMP database to review their patients' utilization reports prior to issuing a prescription for a controlled substance, and by failing to review their own prescriber activity on a semi-annual basis, Respondents violated NRS 453.164(7) and NRS 639.23507.

41. Furthermore, by failing to query the PMP database to review their patients' utilization report prior to issuing a prescription for a controlled substance, and by failing to review their own prescriber activity on a semi-annual basis, each Respondent performed his or her duties as the holder of a certificate issued by the Board in an incompetent, unskillful or negligent manner.

42. As alleged above, each Respondent's conduct constitutes unprofessional conduct for which the Board may impose administrative discipline. NRS 639.210(4); NAC 639.945(1)(i).

COUNT SEVEN
Unprofessional Conduct – Prescribing Without Bona Fide Therapeutic Relationship
(Respondent Bernardi)

43. As alleged above, during the course of Bernardi's employment with Young4Life, a physician's assistant evaluated patients either in-person or via telehealth, and Bernardi reviewed and signed off on patient charts and prescriptions sent under his name.

44. By failing to personally evaluate patients for whom he prescribed controlled substances, Bernardi did not form a bona fide therapeutic relationship as defined in NAC 639.752(4).

45. By permitting the use of his credentials to issue electronic prescriptions for controlled substances to patients with whom he did not have a bona fide therapeutic relationship, Respondent Bernardi engaged in unprofessional conduct and conduct contrary to the public

interest as defined in NAC 639.945(1)(n)(2), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT EIGHT
Violations of Federal and State Law – Recordkeeping
(Respondents Bernardi and Hubbard)

46. As alleged above, by failing to respond to a Board investigator's requests for information and records related to an investigation into their prescribing activities, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.090, NRS 454.286(2), NRS 453.246, NRS 639.239, 21 U.S.C. § 827, 21 CFR § 1311.120(28), 21 CFR § 1304.06, 21 CFR § 1311.305, and 21 CFR § 1311.305, and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11) and/or (12).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of each of the Respondents herein.

DATED this 26th day of AUGUST 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **Mikayla Strief, APRN** **Certificate of Registration No. CS37751,** **JUSTIN SPANGLER, PA** **Certificate of Registration No. CS28770,** **DANIEL INGLISH, DO** **Certificate of Registration No. CS22888,** **Mary Miller-Wilson, APRN** **Certificate of Registration No. CS33703,** **MARK BERNARDI, MD** **Certificate of Registration No. CS29595, and** **TIANA HUBBARD, APRN** **Certificate of Registration No. CS25791,** **Respondents.**	**Case Nos. 24-482-CS-A-S** **24-482-CS-B-S** **24-482-CS-C-S** **24-482-CS-D-S** **24-482-CS-E-S** **24-482-CS-F-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the

Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 25 day of AUGUST 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MARK BERNARDI, MD** **Certificate of Registration No. CS29595,** **Respondent.**	**Case No. 24-482-CS-E-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

MARK BERNARDI, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of August 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Mark Bernardi, MD
c/o Bernardi Medical Group
[redacted]
Las Vegas, NV [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

5V

FILED
AUG 2 8 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MIKAYLA STRIEF, APRN** **Certificate of Registration No. CS37751,** **JUSTIN SPANGLER, PA** **Certificate of Registration No. CS28770,** **DANIEL INGLISH, DO** **Certificate of Registration No. CS22888,** **MARY MILLER-WILSON, APRN** **Certificate of Registration No. CS33703,** **MARK BERNARDI, MD** **Certificate of Registration No. CS29595, and** **TIANA HUBBARD, APRN** **Certificate of Registration No. CS25791,** **Respondents.**	**Case Nos. 24-482-CS-A-S** **24-482-CS-B-S** **24-482-CS-C-S** **24-482-CS-D-S** **24-482-CS-E-S** **24-482-CS-F-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter and these respondents because, at the time of the events alleged herein, Justin Spangler, PA ("Spangler") held a registration issued by the Board, Certificate of Registration No. CS28770; Mikayla Strief, APRN ("Strief") held a registration issued by the Board, Certificate of Registration No. CS37751; Daniel Inglish, DO ("Inglish") held a registration issued by the

Board, Certificate of Registration No. CS22888; Mary Miller-Wilson, APRN ("Miller-Wilson") held a registration issued by the Board, Certificate of Registration No. CS33703; Mark Bernardi, MD ("Bernardi") held a registration issued by the Board, Certificate of Registration No. CS29595; and Tiana Hubbard, APRN ("Hubbard") held a registration issued by the Board, Certificate of Registration No. CS25791.

FACTUAL ALLEGATIONS

2. Respondent Spangler is licensed by the Nevada State Board of Medical Examiners as a physician assistant. At the time of the violations alleged herein, Spangler was a "practitioner" as that term is defined at NRS 453.126(5) and 639.0125(4).

3. Respondents Strief, Miller-Wilson, and Hubbard are licensed by the Nevada State Board of Nursing as advanced practice registered nurses. At the time of the violations alleged herein, Strief, Miller-Wilson, and Hubbard were "practitioners" as that term is defined at NRS 453.126(2) and 639.0125(3).

4. Respondent Inglish is licensed by the Nevada State Board of Osteopathic Medicine as an osteopathic physician. At the time of the violations alleged herein, Inglish was a "practitioner" as that term is defined at NRS 453.126(1) and 639.0125(1).

5. Respondent Bernardi is licensed by the Nevada State Board of Medical Examiners as a physician. At the time of the violations alleged herein, Bernardi was a "practitioner" as that term is defined at NRS 453.126(1) and 639.0125(1).

6. On or about March 2022, David Lindberg ("Lindberg") began operating the wellness clinic D.C.L., LLC, dba Magnus Medical Health and Wellness ("Magnus"), located at 8540 S. Eastern Avenue, Suite 160, in Las Vegas, Nevada. Lindberg is not a licensed practitioner as that term is defined at NRS 453.126(1) and 639.0125(1) and not licensed by the Board or the

Federal Drug Enforcement Administration ("DEA") to possess, administer, prescribe or dispense dangerous drugs or controlled substances.

7. During the relevant timeframe, Respondents Spangler, Strief, Miller-Wilson, Inglish, and Hubbard worked as practitioners at Magnus.

8. On or about September 2024, Lindberg sold Magnus to new owners Donald Min ("Min") and Young Kim ("Kim"), who renamed the business Young4Life. Neither Min nor Kim are licensed practitioners as that term is defined at NRS 453.126(1) and 639.0125(1) or licensed by the Board or DEA to possess, administer, prescribe or dispense dangerous drugs or controlled substances.

9. Min and Kim formed Young4Life in late 2024 and assumed Magnus's established customers and business model. Young4Life retained Lindberg as a marketing consultant.

10. During the relevant timeframe, Respondents Spangler and Bernardi worked as practitioners at Young4Life.

11. A Board investigation found that, as owner of Magnus, between September 2022 and September 2024, Lindberg regularly used several Magnus employees' prescribing credentials to issue prescriptions and access prescribing systems. From September 2024 through at least May 2025, as marketing consultant, Lindberg continued using Young4Life employee's prescribing credentials to issue prescriptions and access prescribing systems.

12. Specifically, during the relevant timeframe, each Respondent permitted Lindberg to access prescribing systems and issue the following controlled substance prescriptions using their electronic prescribing credentials:

A. According to Board records, between May 2024 and November 2024, while employed by Magnus and Young4Life, Spangler authorized 548 controlled

substance prescriptions for 397 unique patients. Furthermore, according to the Board's records, Spangler did not access the PMP database to review his own prescribing activity ("MyRx report") from September 2019 to July 18, 2025. Spangler has only run one patient PMP query, in October 2019.

B. Between May 2024 and November 2024, while employed by Magnus, Strief authorized 170 controlled substance prescriptions for Nevada patients. Strief checked her MyRx report only one time, in December 2024. Strief also did not run any patient PMP queries prior to December 2024.

C. Per company policy, Strief delegated the entire prescribing process to Magnus. As such, Strief sent her prescribing token to Magnus and did not personally authorize any prescriptions for armodafinil, chorionic gonad or ketamine that appeared on her prescribing report from April to November 2024.

D. Between May 2024 and May 2025, while employed by Magnus, Inglish prescribed 63 controlled substances for Nevada patients. Inglish checked his MyRx report two times, in April 2025 and August 2025. He did not check it prior to that date. Inglish has not run any patient PMP queries since June 2022.

E. Between March 2022 and March 2024, while employed by Magnus, Miller-Wilson prescribed 1,846 controlled substances for 714 unique Nevada patients. Miller-Wilson checked her MyRx report once in October 2023. She has been compliant in checking her MyRx report since October 2024.

F. Per company policy, Miller-Wilson delegated the entire prescribing process to Magnus.

G. Between February 2025 and June 25, 2025, while employed by Young4Life, Bernardi prescribed 327 controlled substances for 203 unique Nevada patients. Bernardi has not checked his MyRx report from June 2022 and July 2025. Bernardi did not run any patient PMP queries prior to August 4, 2025.

H. Per company policy at Young4Life, Spangler or another physician's assistant would evaluate patients, generally via telehealth. Bernardi would then sign off on patient charts and prescriptions that were sent via his electronic credentials. Bernardi delegated the issuing of electronic prescriptions to someone else at Young4Life.

I. Between February 2023 and March 2024, while employed by Magnus, Hubbard prescribed 381 controlled substances for 202 unique Nevada patients. Hubbard checked her MyRx report only one time, in October 2024. She has not run any patient PMP queries between April 2019 and May 2025.

13. Between June 30, 2025 through August 20, 2025, Board Investigator Dena McClish (McClish) attempted to communicate with Bernardi to discuss his patient records and employment at Young4Life. Although Bernardi indicated that he would cooperate with McClish's investigation, he ultimately failed to respond to her requests for information.

14. On or about July 1, 2025, McClish attempted to contact Hubbard through certified and regular U.S. Mail and e-mail about her patient records and employment with Magnus. Hubbard failed to respond to her requests for information.

\\\

\\\

\\\

PRIOR DISCIPLINE

15. On December 3, 2025, the Board disciplined Respondent Inglish for allowing unlicensed individuals independent access to dangerous drugs; allowing unlicensed individuals to access, possess, furnish, and administer dangerous drugs; permitting the administration of patient-specific prescription medications to multiple patients; intermingling of adulterated and expired drugs; falsifying prescriptions; and aiding and abetting unlicensed practice. The Board placed Respondent Inglish on one-year probation beginning on December 3, 2025, and ordered him to pay a $5,000 fine and $1,000 in fees and costs.

APPLICABLE LAW

16. Pursuant to NRS 639.100(1), it is unlawful for any person to manufacture, engage in wholesale distribution, compound, sell or dispense, or permit to be manufactured, distributed at wholesale, compounded, sold or dispensed, any drug, poison, medicine or chemical, or to dispense or compound, or permit to be dispensed or compounded drugs without having secured the appropriate license and/or certificate of registration from the Board.

17. Falsifying a prescription for a controlled substance is a felony offense. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1).

18. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession, to a patient with whom the practitioner has established a bona fide therapeutic relationship. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a); 21 CFR § 1306.04(a); NRS 453.381(1); NRS 639.235(1); NRS 639.23911(1)(a); NRS 639.2813(1).

19. A practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor, or biometric information, with any other person. The practitioner must not allow any other person to use the token or enter the knowledge factor or other identification means to sign prescriptions for controlled substances. 21 CFR § 1311.102 and NAC 639.7105(2)(b).

20. The Controlled Substances Act imposes strict liability on registrants to provide effective controls and procedures to guard against theft and diversion, which includes the duty to safeguard prescribing credentials from unauthorized use. *See* 21 CFR 1301.71(a). 21 U.S.C. § 843(a)(2) criminalizes the use of another person's DEA registration number

21. A practitioner shall, before issuing an initial prescription for a controlled substance, and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the PMP. NRS 639.23507.

22. A practitioner registered with the Board to write prescriptions for controlled substances must access his or her prescriber activity in the PMP at least once every 6 months to review prescriptions issued by the practitioner and to verify for the Board that he or she continues to have access to the PMP. NRS 453.164(7).

23. Any licensee registered with the Board must provide access to all records of sale and disposition of drugs, medicines or poisons or devices or appliances that are restricted by federal law to sale by or on the order of a physician, to members of the Board, its inspectors, and investigators. NRS 639.090. *See also* NRS 639.239 (duty to provide prescription records); NRS 453.246 (records related to controlled substances).

24. Every practitioner who engages in the practicing of furnishing dangerous drugs to patients shall maintain a complete and accurate record of all dangerous drugs purchased and those sold on prescription, dispensed, furnished or disposed of otherwise. NRS 454.286(1). The records must be retained for a period of 2 years and must be open to inspection by members, inspectors or investigators of the Board. NRS 454.286(2). *See also* 21 U.S.C. § 827 (recordkeeping requirements by registrants); 21 CFR § 1304.06 and 21 CFR § 1311.305 (regarding electronic prescription records).

25. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1)(e) and NRS 639.210(4).

26. Prescribing a drug to any patient with whom the prescribing practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n)(2) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4). A bona fide relationship shall be deemed to exist if the patient was examined in person, electronically, telephonically or by fiber optics within or outside of this State or the United States by the practitioner within the 6 months immediately preceding the date the prescription was issued. NAC 639.752.

27. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

28. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

29. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

30. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

31. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 upon a finding that the registrant has committed an act that renders registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Unprofessional Conduct -Party to Fraudulent or Deceitful Practice or Transaction by Permitting Use of Credentials
(All Respondents)

32. As alleged above, by permitting Lindberg to use their credentials and act under their authority to fraudulently issue prescriptions for controlled substances, each Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(l)(e), NRS 453.241(1) and/or NRS 639.210(4).

\\\

\\\

COUNT TWO

Unprofessional Conduct -Incompetent, Unskillful or Negligent Performance of Duties by Allowing Prescribing Credentials to be Compromised
(All Respondents)

33. As alleged above, to the extent each Respondent's electronic prescribing credentials were compromised and resulted in the unlawful issuance of fraudulent controlled substance prescriptions by a third party, Respondents failed to comply with 21 CFR § 1311.102, NRS 453.164(7) and NAC 639.7105(2)(b), performed their duties as the holder of a Nevada controlled substance registration in an incompetent, unskillful or negligent manner, and engaged in unprofessional conduct as defined in NAC 639.945(1)(i), committed acts that render their registration inconsistent with the public interest, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(4), (11) and (12).

COUNT THREE

Violations of Federal Controlled Substances Act – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(All Respondents)

34. As alleged above, by permitting Lindberg to use their credentials and act under their authority to issue electronic prescriptions for controlled substances, each Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 CFR 1301.71(a). 21 U.S.C. § 843(a)(2),21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 846, 21 CFR § 1306.03(a), 21 CFR § 1306.04(a), 21 CFR § 1311.100 and/or 21 CFR § 1311.102 and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1) and/or NRS 639.210(11).

\\\

\\\

\\\

COUNT FOUR

Unprofessional Conduct – Assisting or abetting unlicensed practice
(All Respondents)

35. As alleged above, Lindberg did not have licensure from the Board as required by NRS 639.100(1) when he used each Respondent's credential and acted under their authority to issue electronic prescriptions for controlled substances.

36. By assisting and abetting Lindberg's unlicensed activity, each Respondent engaged in unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(j), and is subject to discipline pursuant to NRS 639.210(4).

COUNT FIVE

Violations of State Law – Unlawfully Issuing Electronic Prescriptions for Controlled Substances
(All Respondents)

37. As alleged above, by permitting Lindberg to use their credentials and act under their authority to issue electronic prescriptions for controlled substances, each Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.381(1), NRS 453.385, NRS 453.401(l)(a), NRS 639.235(1), NRS 639.23535, NRS 639.23911(1)(a), NRS 639.2813(1) and/or NAC 639.7105, and is subject to discipline pursuant to NRS 453.236(1)(d) and (e), NRS 453.241(1), NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT SIX

Unprofessional Conduct by a Practitioner – Failure to Query PMP Database
(All Respondents)

38. As alleged above, each Respondent failed to query the PMP database regarding his or her patients' histories of using controlled substances as required by law. NRS 639.23507.

39. As alleged above, each Respondent failed to query the PMP database regarding his or her own prescriber activity as required by law. NRS 453.164(7).

40. By failing to query the PMP database to review their patients' utilization reports prior to issuing a prescription for a controlled substance, and by failing to review their own prescriber activity on a semi-annual basis, Respondents violated NRS 453.164(7) and NRS 639.23507.

41. Furthermore, by failing to query the PMP database to review their patients' utilization report prior to issuing a prescription for a controlled substance, and by failing to review their own prescriber activity on a semi-annual basis, each Respondent performed his or her duties as the holder of a certificate issued by the Board in an incompetent, unskillful or negligent manner.

42. As alleged above, each Respondent's conduct constitutes unprofessional conduct for which the Board may impose administrative discipline. NRS 639.210(4); NAC 639.945(1)(i).

COUNT SEVEN
Unprofessional Conduct – Prescribing Without Bona Fide Therapeutic Relationship
(Respondent Bernardi)

43. As alleged above, during the course of Bernardi's employment with Young4Life, a physician's assistant evaluated patients either in-person or via telehealth, and Bernardi reviewed and signed off on patient charts and prescriptions sent under his name.

44. By failing to personally evaluate patients for whom he prescribed controlled substances, Bernardi did not form a bona fide therapeutic relationship as defined in NAC 639.752(4).

45. By permitting the use of his credentials to issue electronic prescriptions for controlled substances to patients with whom he did not have a bona fide therapeutic relationship, Respondent Bernardi engaged in unprofessional conduct and conduct contrary to the public

interest as defined in NAC 639.945(1)(n)(2), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT EIGHT
Violations of Federal and State Law – Recordkeeping
(Respondents Bernardi and Hubbard)

46. As alleged above, by failing to respond to a Board investigator's requests for information and records related to an investigation into their prescribing activities, Respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.090, NRS 454.286(2), NRS 453.246, NRS 639.239, 21 U.S.C. § 827, 21 CFR § 1311.120(28), 21 CFR § 1304.06, 21 CFR § 1311.305, and 21 CFR § 1311.305, and are subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11) and/or (12).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of each of the Respondents herein.

DATED this 28th day of AUGUST 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **Mikayla Strief, APRN** **Certificate of Registration No. CS37751,** **JUSTIN SPANGLER, PA** **Certificate of Registration No. CS28770,** **DANIEL INGLISH, DO** **Certificate of Registration No. CS22888,** **Mary Miller-Wilson, APRN** **Certificate of Registration No. CS33703,** **MARK BERNARDI, MD** **Certificate of Registration No. CS29595, and** **TIANA HUBBARD, APRN** **Certificate of Registration No. CS25791,** **Respondents.**	**Case Nos. 24-482-CS-A-S** **24-482-CS-B-S** **24-482-CS-C-S** **24-482-CS-D-S** **24-482-CS-E-S** **24-482-CS-F-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the

Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 22nd day of AUGUST 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **TIANA HUBBARD, APRN** **Certificate of Registration No. CS25791,** **Respondent.**	**Case No. 24-482-CS-F-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

TIANA HUBBARD, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 28th day of August 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Tiana Hubbard, APRN
c/o Kalologie Medspa
3730 S Las Vegas Blvd.
Las Vegas, NV 89158

And via Electronic Mail to: [redacted]@gmail.com

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

5W

FILED
MAR 30 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AURELIA HURTADA-SADOWSKI, RPH, Certificate of Registration No. 15345, and** **SUMMERLIN HOSPITAL MEDICAL CENTER, License No. IA02194,** **Respondents.**	**Case No. 25-209-RPH-S** **25-209-PH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Aurelia Hurtada-Sadowski, RPh, (Hurtada-Sadowski), Certificate of Registration No. 15345, was a pharmacist licensed by the Board, and Respondent Summerlin Hospital Medical Center (Summerlin Hospital), License No. IA02194, was registered as a pharmacy by the Board.

FACTUAL ALLEGATIONS

2. Hurtada-Sadowski was employed as a pharmacist at Summerlin Hospital, located at 653 N. Town Center Drive in Las Vegas, at the time of the events alleged herein.

3. On May 5, 2025, patient J.B. arrived at the emergency department of Summerlin Hospital and reported that she was experiencing symptoms of an acute multiple sclerosis flare up.

4. Alexander Payne, MD, (Payne) was the medical practitioner on duty when patient J.B. arrived.

5. Patient J.B. informed Payne that she wanted to be treated with Solu-Medrol (methylprednisolone). Patient J.B. told Payne that she had had an allergic reaction to Solu-Medrol in the past, but that she had been able to tolerate it when pre-treated with Benadryl.

6. After consultation with patient J.B., Payne submitted an order for methylprednisolone 125 mg administered via IV piggyback along with Benadryl 50 mg 1 ML administered via IV push.

7. When submitting the order, Payne did not enter into the patient's chart that she had a known allergy to methylprednisolone and did not include any other notes. The order also did not contain a diluent or volume, as is required for an IV piggyback.

8. Hurtada-Sadowski was the pharmacist on duty at the time Payne submitted the order. While Hurtada-Sadowski was processing the order, she received a prompt generated by the computer system indicating that an IV push was the standard practice for methylprednisolone 125 mg.

9. Because the chart order was incomplete, Summerlin Hospital's system would not allow Hurtada-Sadowski to release the product without making a change.

10. Hurtada-Sadowski did not contact or notify Payne about the missing information regarding administration route or lack of accompanying notations and changed the order for methylprednisolone to IV push instead of IV piggyback to reflect the computer's prompting.

11. Registered Nurse George Maldonado (Maldonado) received the order back from Hurtada-Sadowski and pushed 0.55 cc of methylprednisolone over 30 seconds, then paused to assess.

12. After the initial medication push, patient J.B. reported anaphylactic symptoms, and Maldonado contacted Payne, who began treating patient J.B. for anaphylaxis.

13. Despite intervention, patient J.B. was placed on life support that night. She was not taken off life support and died two days later, on May 7, 2025. The cause of death was listed as multisystem organ failure due to cardiac arrest secondary to anaphylaxis.

14. Summerlin Hospital terminated Hurtada-Sadowski a few months later.

PRIOR DISCIPLINE

15. In December 2008, the Board disciplined an employee of Respondent Summerlin Hospital for diversion of controlled substances, resulting in the revocation of the employee's license.

16. In April 2008, the Board disciplined Respondent Summerlin Hospital for the death of an infant patient because of drug overdose, resulting in a $10,000 fine to Respondent Summerlin Hospital.

APPLICABLE LAW

17. Medical facilities must have original chart orders that contain, among other information, the name of the drug, its strength, and the route of administration, as well as directions for use of the drug. NAC 639.484(1)(b),(c).

18. Pursuant to NAC 639.753, a pharmacist may use his or her professional judgment to reasonably decline to fill a prescription after speaking with the prescribing practitioner in a timely manner to discuss and resolve the concerns the pharmacist has regarding the prescription.

19. Pharmacists have a duty to exercise independent judgment regarding patient care pursuant to NAC 639.753.

20. Unprofessional conduct includes a registrant performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i). The Board may suspend or revoke any certificate, license, registration or permit if the holder is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

21. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license by the Board. NRS 639.230(5); NAC 639.702. Furthermore, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

22. The Board may discipline a licensee who has violated any provisions of a regulation relating to the practice of pharmacy. NRS 639.210(12).

23. In lieu of, or in addition to, revoking or suspending a license holder's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

COUNT ONE
Unprofessional Conduct by a Pharmacist – Failure to Confer with Healthcare Provider (Respondent Hurtada-Sadowski)

24. As alleged above, on or about May 5, 2025, Respondent Hurtada-Sadowski received a chart that did not contain complete information as required by NAC 639.484(1)(b),(c).

25. As alleged above, Respondent Hurtada-Sadowski filled the chart order for patient J.B. even though she knew or should have known to contact Payne about the incomplete chart order when she received conflicting information from the hospital computer system. Respondent Hurtada-Sadowski's conduct was unprofessional because she failed to confer with patient J.B.'s health care provider regarding the incomplete chart order. NAC 639.753.

26. Having failed to confer directly with a patient's health care provider and changing the chart order of the patient's health care provider, Respondent Hurtada-Sadowski performed her duties in an incompetent, unskillful or negligent manner.

27. Respondent Hurtada-Sadowski's unprofessional conduct may have contributed to patient J.B.'s death.

28. For this unprofessional conduct, the Board may discipline Respondent Hurtada-Sadowski pursuant to NRS 639.210(4), NRS 639.255(1), NAC 639.945, and NAC 639.955.

\\\

\\\

\\\

\\\

COUNT TWO
Pharmacy Owner Responsibility
(Respondent Summerlin Hospital)

29. As alleged above, on or about May 5, 2025, Respondent Hurtada-Sadowski changed the chart order for patient J.B. even though she knew or should have known to contact Payne about the incomplete chart order when she received conflicting information from the hospital computer system. Respondent Hurtada-Sadowski's conduct was unprofessional because she failed to confer with patient J.B.'s health care provider regarding the incomplete chart order. Having failed to confer directly with a patient's health care provider and changing the chart order of the patient's health care provider, Respondent Hurtada-Sadowski performed her duties in an incompetent, unskillful or negligent manner.

30. As alleged above, Respondent Summerlin Hospital's computer system would not allow Hurtada-Sadowski to release the chart order without making a change to the order.

31. As the facility at which the unprofessional conduct and violations of law alleged herein occurred, Respondent Summerlin Hospital is responsible for those violations, including all errors and omissions of Respondent Hurtada-Sadowski, Payne, and any other personnel in the course of violations of any law or regulation related to the practice of pharmacy, pursuant NAC 639.945(3). Accordingly, the Board may discipline Summerlin Hospital pursuant to NRS 639.210(4), NRS 639.255(1), NAC 639.945, and NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of Respondents Aurelia Hurtada-Sadowski and Summerlin Hospital Medical Center.

DATED this 30th day of MARCH 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SUMMERLIN HOSPITAL MEDICAL CENTER, License No. IA02194,** **Respondent.**	**Case No. 25-209-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, June 3, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 30th day of MARCH 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **SUMMERLIN HOSPITAL MEDICAL CENTER, License No. IA02194,** **Respondent.**	**Case No. 25-209-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

AUTHORIZED REPRESENTATIVE FOR
Summerlin Hospital Medical Center

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 30th day of March 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Aurelia Hurtada-Sadowski, RPh
[redacted]
Las Vegas, NV [redacted]

Summerlin Hospital Medical Center Pharmacy
c/o Aurelia Hurtada-Sadowski, RPh
657 N. Town Center Dr
Las Vegas, NV 89144

Summerlin Hospital Medical Center Pharmacy
657 N. Town Center Dr
Las Vegas, NV 89144

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of June 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Summerlin Hospital Medical Center Pharmacy
c/o Jessica Gandy, Esq.
Peccole Professional Park
10080 West Alta Dr, Suite 200
Las Vegas, NV 89145

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
MAY 10 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, v. AURELIA HURTADA-SADOWSKI, RPH, Certificate of Registration No. 15345, and SUMMERLIN HOSPITAL MEDICAL CENTER, License No. IA02194, Respondents.	Case No. 25-209-RPH-S 25-209-PH-S

ANSWER TO COMPLAINT

Respondent, SUMMERLIN HOSPITAL MEDICAL CENTER, ("SHMC" or "Respondent") by and through its counsel of record, HUTCHISON & STEFFEN, PLLC, answers the Complaint as follows:

JURISDICTION

1. Answering Paragraph 1 of the Complaint, Respondent admits it is registered as a pharmacy by the Board. As to the remaining allegations, Respondent states that it is without knowledge and or information sufficient to form a belief as to the truth of the remaining allegations contained in said paragraph and therefore denies the allegations contained therein.

FACTUAL ALLEGATIONS

2. Answering Paragraph 2 of the Complaint, Respondent admits the allegations contained in said paragraph.

3. Answering Paragraph 3 of the Complaint, Respondent admits the allegations contained in said paragraph to the extent that it is consistent with the medical records; to the extent that the allegations differ or extrapolate upon the medical records, Respondent states that it is without knowledge and or information sufficient to form a belief as to the truth of the allegations

contained in said paragraph and therefore denies the allegations contained therein.

4. Answering Paragraph 4 of the Complaint, Respondent admits the allegations contained in said paragraph to the extent that it is consistent with the medical records; to the extent that the allegations differ or extrapolate upon the medical records, Respondent states that it is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

5. Answering Paragraph 5 of the Complaint, Respondent admits the allegations contained in said paragraph to the extent that it is consistent with the medical records; to the extent that the allegations differ or extrapolate upon the medical records, Respondent states that it is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

6. Answering Paragraph 6 of the Complaint, Respondent admits the allegations contained in said paragraph to the extent that it is consistent with the medical records; to the extent that the allegations differ or extrapolate upon the medical records, Respondent states that it is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

7. Answering Paragraph 7 of the Complaint, Respondent admits the allegations contained in said paragraph to the extent that it is consistent with the medical records; to the extent that the allegations differ or extrapolate upon the medical records, Respondent states that it is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

8. Answering Paragraph 8 of the Complaint, Respondent admits Hurtada-Sadowski was the pharmacist on duty at the time Payne submitted the order. As to the remaining allegations, Respondent states that it is without knowledge and or information sufficient to form a belief as to the truth of the remaining allegations contained in said paragraph and therefore denies the allegations contained therein.

9. Answering Paragraph 9 of the Complaint, Respondent states that it is without knowledge and or information sufficient to form a belief as to the truth of the remaining allegations contained in said paragraph and therefore denies the allegations contained therein.

10. Answering Paragraph 10 of the Complaint, Respondent states that it is without knowledge and or information sufficient to form a belief as to the truth of the remaining allegations contained in said paragraph and therefore denies the allegations contained therein.

11. Answering Paragraph 11 of the Complaint, Respondent admits the allegations contained in said paragraph to the extent that it is consistent with the medical records; to the extent that the allegations differ or extrapolate upon the medical records, Respondent states that it is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

12. Answering Paragraph 12 of the Complaint, Respondent admits the allegations contained in said paragraph to the extent that it is consistent with the medical records; to the extent that the allegations differ or extrapolate upon the medical records, Respondent states that it is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

13. Answering Paragraph 13 of the Complaint, Respondent admits the allegations contained in said paragraph to the extent that it is consistent with the medical records; to the extent that the allegations differ or extrapolate upon the medical records, Respondent states that it is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

14. Answering Paragraph 14 of the Complaint, Respondent admits the allegations contained in said paragraph.

PRIOR DISCIPLINE

15. Answering Paragraph 15 of the Complaint, Respondent states the paragraph is a restatement of statute and does not contain any factual allegations that can be admitted or denied.

To the extent that the allegations differ or extrapolate upon the statute, Respondent states that she is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

16. Answering Paragraph 16 of the Complaint, Respondent admits the allegations contained in said paragraph.

APPLICABLE LAW

17. Answering Paragraph 17 of the Complaint, Respondent states the paragraph is a restatement of statute and does not contain any factual allegations that can be admitted or denied. To the extent that the allegations differ or extrapolate upon the statute, Respondent states that she is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

18. Answering Paragraph 18 of the Complaint, Respondent states the paragraph is a restatement of statute and does not contain any factual allegations that can be admitted or denied. To the extent that the allegations differ or extrapolate upon the statute, Respondent states that she is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

19. Answering Paragraph 19 of the Complaint, Respondent states the paragraph is a restatement of statute and does not contain any factual allegations that can be admitted or denied. To the extent that the allegations differ or extrapolate upon the statute, Respondent states that she is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

20. Answering Paragraph 20 of the Complaint, Respondent states the paragraph is a restatement of statute and does not contain any factual allegations that can be admitted or denied. To the extent that the allegations differ or extrapolate upon the statute, Respondent states that she is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

21. Answering Paragraph 21 of the Complaint, Respondent states the paragraph is a restatement of statute and does not contain any factual allegations that can be admitted or denied. To the extent that the allegations differ or extrapolate upon the statute, Respondent states that she is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

22. Answering Paragraph 22 of the Complaint, Respondent states the paragraph is a restatement of statute and does not contain any factual allegations that can be admitted or denied. To the extent that the allegations differ or extrapolate upon the statute, Respondent states that she is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

23. Answering Paragraph 23 of the Complaint, Respondent states the paragraph is a restatement of statute and does not contain any factual allegations that can be admitted or denied. To the extent that the allegations differ or extrapolate upon the statute, Respondent states that she is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

COUNT ONE

Unprofessional Conduct by a Pharmacist – Failure to Confer with Healthcare Provider (Respondent Hurtada-Sadowski)

24. Answering Paragraph 24 of the Complaint, Respondent states the paragraph is a restatement of statute and does not contain any factual allegations that can be admitted or denied. To the extent that the allegations differ or extrapolate upon the statute, Respondent states that it is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

25. Answering Paragraph 25 of the Complaint, Respondent states said paragraph calls for an expert opinion to which no response is required. To the extent a response is required, Respondent states that he is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations

contained therein.

26. Answering Paragraph 26 of the Complaint, Respondent states said paragraph calls for an expert opinion to which no response is required. To the extent a response is required, Respondent states that he is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

27. Answering Paragraph 27 of the Complaint, Respondent denies the allegations contained in said paragraph.

28. Answering Paragraph 28 of the Complaint, Respondent states said paragraph calls for an expert opinion to which no response is required. To the extent a response is required, Respondent states that he is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

COUNT TWO
Pharmacy Owner Responsibility
(Respondent Summerlin Hospital)

29. Answering Paragraph 29 of the Complaint, Respondent states said paragraph calls for an expert opinion to which no response is required. To the extent a response is required, Respondent states that it is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations contained therein.

30. Answering Paragraph 30 of the Complaint, Respondent admits the allegations contained in said paragraph.

31. Answering Paragraph 31 of the Complaint, Respondent states said paragraph calls for an expert opinion to which no response is required. To the extent a response is required, Respondent states that it is without knowledge and or information sufficient to form a belief as to the truth of the allegations contained in said paragraph and therefore denies the allegations

contained therein.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The Complaint fails to state claims against SHMC upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The Complaint does not give SHMC the necessary and appropriate notice of claims against it, which is a violation of SHMC's due process rights.

THIRD AFFIRMATIVE DEFENSE

The injuries, if any, complained of in the Complaint were proximately caused by the acts or omissions of unknown third parties or other persons over whom SHMC exercised no control, and over whom SHMC had no right or duty to control, nor ever had a right or duty to exercise control.

FOURTH AFFIRMATIVE DEFENSE

The damages, if any, alleged were not the result of any acts of omission, or commission, or negligence, but were the result of a known risk which was consented to by Patient J.B. and his/her family/caregivers, such risks being inherent in the nature of the care rendered and such risks were assumed by Patient J.B. and his/her family/caregivers when they consented to treatment.

FIFTH AFFIRMATIVE DEFENSE

In all medical care rendered by SHMC to Patient J.B., SHMC possessed and exercised that degree of skill and learning ordinarily possessed and exercised by the members of its profession in good standing, practicing in similar localities, and that at all times SHMC used reasonable care and diligence in the exercise of its skills and the application of its learning, and at all times acted according to its best judgment; that the medical treatment administered by SHMC was the usual and customary treatment for the physical condition and symptoms exhibited by Patient J.B. and that at no time was SHMC guilty of negligence or improper treatment, that, on the contrary, SHMC did perform each and every act of such treatment in a proper and efficient manner and in a manner

most thoroughly approved and followed by the medical profession generally and under the circumstances and conditions as they existed when such medical attention was rendered.

SIXTH AFFIRMATIVE DEFENSE

At all times mentioned in the Complaint, Patient J.B. was suffering from a medical condition(s) that SHMC did not cause, nor was SHMC responsible for said medical condition(s).

SEVENTH AFFIRMATIVE DEFENSE

Patient J.B.'s maladies and injuries, if any, were caused by inevitable disease processes and not by any act of this Respondent.

EIGHTH AFFIRMATIVE DEFENSE

The injuries complained of in the Complaint, if any, were not the result of willful, malicious or deliberate conduct on the part of SHMC.

NINTH AFFIRMATIVE DEFENSE

SHMC denies each and every allegation of the Board's Complaint not specifically admitted or otherwise pled to herein.

TENTH AFFIRMATIVE DEFENSE

All possible Affirmative Defenses may not have been alleged herein insofar as sufficient facts were not available after reasonable inquiry upon the filing of SHMC's Answer, and therefore, SHMC reserves the right to amend its Answer to allege additional Affirmative Defenses if subsequent investigation warrants.

ELEVENTH AFFIRMATIVE DEFENSE

The damages, if any, alleged in the Board's Complaint are not the result of any acts of omission, commission, or negligence, but were the result of a known risk(s), which was consented to by Patient J.B.

TWELFTH AFFIRMATIVE DEFENSE

SHMC hereby incorporates by reference those affirmative defenses enumerated in NRCP 8 and 12, as if fully set forth herein. In the event further investigation or discovery reveals the

applicability of any such defenses, Respondent reserves the right to seek leave of Court to amend her Answer to specifically assert any such defense(s). Such defenses are herein incorporated by reference for the specific purpose of not waiving any such defense.

THIRTEENTH AFFIRMATIVE DEFENSE

It has been necessary for SHMC to employ the services of an attorney to defend this action and a reasonable sum should be allowed to Respondent for attorneys' fees, together with costs of suit incurred herein.

PRAYER FOR RELIEF

WHEREFORE, SHMC prays for judgment as follows:

1. That the Board takes nothing by virtue of its Complaint, and that all allegations against SHMC are dismissed with prejudice;

2. For reasonable attorneys' fees and costs of suit incurred herein;

3. For costs and disbursements incurred herein; and

4. For such other and further relief as is just and proper.

DATED this 1st day of May 2026.

HUTCHISON & STEFFEN, PLLC

/s/ Jessica R. Gandy

Candace C. Herling, Esq. (NBN. 13503)
Jessica R. Gandy, Esq. (NBN 14202)
Peccole Professional Park
10080 West Alta Drive, Suite 200
Las Vegas, NV 89145
Telephone: (702) 385-2500
Attorneys for Respondent
Summerlin Hospital Medical Center

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AURELIA HURTADA-SADOWSKI, RPH, Certificate of Registration No. 15345, and** **SUMMERLIN HOSPITAL MEDICAL CENTER, License No. IA02194,** **Respondents.**	**CASE NOS. 25-209-RPH-S** **25-209-PH-S** **STIPULATION AND ORDER [SUMMERLIN HOSPITAL MEDICAL CENTER ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through counsel, Laura M. Tucker, Esq., and Summerlin Hospital Medical Center, License No. IA02194, ("Respondent"), by and through counsel, Jessica R. Gandy, Esq., hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of

this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. For the purposes of resolving this matter, without admitting to the alleged facts or legal conclusions, Respondent acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation, *to wit*:

A. On or about May 5, 2025, Aurelia Hurtada-Sadowski (Hurtada-Sadowski), while employed as a pharmacist by Respondent, received a chart that did not contain complete information as required by NAC 639.484(1)(b),(c).

B. Hurtada-Sadowski engaged in unprofessional conduct as defined in NAC 639.945 when she failed to confer directly with a patient's health care provider and changed the chart order of the patient's health care provider.

C. Respondent's computer system would not allow Hurtada-Sadowski to release the chart order without making a change to the order.

D. As the facility at which the unprofessional conduct and violations of law alleged herein occurred, Respondent is responsible for those violations, including all errors and omissions of Hurtada-Sadowski and any other personnel in the course of violations of any law or regulation related to the practice of pharmacy, pursuant NAC 639.945(3). Accordingly, the Board may discipline Respondent pursuant to NRS 639.210(4), NRS 639.255(1), NAC 639.945, and NAC 639.955.

7. Those violations are pled with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

8. Now, therefore, to resolve the allegations stated in Count Two of the Accusation without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent shall pay an administrative fine of **Seven Thousand Five Hundred and 00/100 Dollars ($7,500.00)**, payable by *personal, business, certified or cashier's check or money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Stipulation.

B. Respondent shall pay the sum of **One Thousand Five Hundred and 00/100 Dollars ($1,500.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *personal, business, certified or cashier's check or money order* written to the "**Nevada State Board of Pharmacy.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Stipulation.

C. Within 60 days of the date of the order, Respondent must provide the Board staff with a copy of its updated policy related to the hospital's medication administration policy, including the administration of injectable medications and how pharmacists proceed with incorrect or incomplete medication orders.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 14, 2026. Respondent will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

//

//

//

//

//

//

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 24 day of Sept. 2026

Summerlin Hospital Medical Center

By: _____
Name : Robert Freymuller
Title: CEO

Signed this ____ day of _____ 2026

Nevada State Board of Pharmacy

By _____
LAURA M. TUCKER, ESQ.
Senior General Counsel

Signed this 29 day of _____ 2026
Approved as to Form and Content:

_____
JESSICA R. GANDY, ESQ.
Hutchison & Steffen, PLLC
Attorney for Respondent Summerlin Hospital Medical Center

DECISION AND ORDER

As to Summerlin Hospital Medical Center, in Case No. 25-209-PH-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this ____day of October 2026.

Helen Park, President
Nevada State Board of Pharmacy

5X

FILED
MAR 30 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AURELIA HURTADA-SADOWSKI, RPH, Certificate of Registration No. 15345, and** **SUMMERLIN HOSPITAL MEDICAL CENTER, License No. IA02194,** **Respondents.**	**Case No. 25-209-RPH-S** **25-209-PH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Aurelia Hurtada-Sadowski, RPh, (Hurtada-Sadowski), Certificate of Registration No. 15345, was a pharmacist licensed by the Board, and Respondent Summerlin Hospital Medical Center (Summerlin Hospital), License No. IA02194, was registered as a pharmacy by the Board.

FACTUAL ALLEGATIONS

2. Hurtada-Sadowski was employed as a pharmacist at Summerlin Hospital, located at 653 N. Town Center Drive in Las Vegas, at the time of the events alleged herein.

3. On May 5, 2025, patient J.B. arrived at the emergency department of Summerlin Hospital and reported that she was experiencing symptoms of an acute multiple sclerosis flare up.

4. Alexander Payne, MD, (Payne) was the medical practitioner on duty when patient J.B. arrived.

5. Patient J.B. informed Payne that she wanted to be treated with Solu-Medrol (methylprednisolone). Patient J.B. told Payne that she had had an allergic reaction to Solu-Medrol in the past, but that she had been able to tolerate it when pre-treated with Benadryl.

6. After consultation with patient J.B., Payne submitted an order for methylprednisolone 125 mg administered via IV piggyback along with Benadryl 50 mg 1 ML administered via IV push.

7. When submitting the order, Payne did not enter into the patient's chart that she had a known allergy to methylprednisolone and did not include any other notes. The order also did not contain a diluent or volume, as is required for an IV piggyback.

8. Hurtada-Sadowski was the pharmacist on duty at the time Payne submitted the order. While Hurtada-Sadowski was processing the order, she received a prompt generated by the computer system indicating that an IV push was the standard practice for methylprednisolone 125 mg.

9. Because the chart order was incomplete, Summerlin Hospital's system would not allow Hurtada-Sadowski to release the product without making a change.

10. Hurtada-Sadowski did not contact or notify Payne about the missing information regarding administration route or lack of accompanying notations and changed the order for methylprednisolone to IV push instead of IV piggyback to reflect the computer's prompting.

11. Registered Nurse George Maldonado (Maldonado) received the order back from Hurtada-Sadowski and pushed 0.55 cc of methylprednisolone over 30 seconds, then paused to assess.

12. After the initial medication push, patient J.B. reported anaphylactic symptoms, and Maldonado contacted Payne, who began treating patient J.B. for anaphylaxis.

13. Despite intervention, patient J.B. was placed on life support that night. She was not taken off life support and died two days later, on May 7, 2025. The cause of death was listed as multisystem organ failure due to cardiac arrest secondary to anaphylaxis.

14. Summerlin Hospital terminated Hurtada-Sadowski a few months later.

PRIOR DISCIPLINE

15. In December 2008, the Board disciplined an employee of Respondent Summerlin Hospital for diversion of controlled substances, resulting in the revocation of the employee's license.

16. In April 2008, the Board disciplined Respondent Summerlin Hospital for the death of an infant patient because of drug overdose, resulting in a $10,000 fine to Respondent Summerlin Hospital.

APPLICABLE LAW

17. Medical facilities must have original chart orders that contain, among other information, the name of the drug, its strength, and the route of administration, as well as directions for use of the drug. NAC 639.484(1)(b),(c).

18. Pursuant to NAC 639.753, a pharmacist may use his or her professional judgment to reasonably decline to fill a prescription after speaking with the prescribing practitioner in a timely manner to discuss and resolve the concerns the pharmacist has regarding the prescription.

19. Pharmacists have a duty to exercise independent judgment regarding patient care pursuant to NAC 639.753.

20. Unprofessional conduct includes a registrant performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i). The Board may suspend or revoke any certificate, license, registration or permit if the holder is guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4).

21. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license by the Board. NRS 639.230(5); NAC 639.702. Furthermore, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

22. The Board may discipline a licensee who has violated any provisions of a regulation relating to the practice of pharmacy. NRS 639.210(12).

23. In lieu of, or in addition to, revoking or suspending a license holder's registration for violating the law or engaging in unprofessional conduct, the Board may impose fines as a disciplinary measure. *See* NRS 639.255; NAC 639.955.

COUNT ONE
Unprofessional Conduct by a Pharmacist – Failure to Confer with Healthcare Provider (Respondent Hurtada-Sadowski)

24. As alleged above, on or about May 5, 2025, Respondent Hurtada-Sadowski received a chart that did not contain complete information as required by NAC 639.484(1)(b),(c).

25. As alleged above, Respondent Hurtada-Sadowski filled the chart order for patient J.B. even though she knew or should have known to contact Payne about the incomplete chart order when she received conflicting information from the hospital computer system. Respondent Hurtada-Sadowski's conduct was unprofessional because she failed to confer with patient J.B.'s health care provider regarding the incomplete chart order. NAC 639.753.

26. Having failed to confer directly with a patient's health care provider and changing the chart order of the patient's health care provider, Respondent Hurtada-Sadowski performed her duties in an incompetent, unskillful or negligent manner.

27. Respondent Hurtada-Sadowski's unprofessional conduct may have contributed to patient J.B.'s death.

28. For this unprofessional conduct, the Board may discipline Respondent Hurtada-Sadowski pursuant to NRS 639.210(4), NRS 639.255(1), NAC 639.945, and NAC 639.955.

\\\

\\\

\\\

\\\

COUNT TWO
Pharmacy Owner Responsibility
(Respondent Summerlin Hospital)

29. As alleged above, on or about May 5, 2025, Respondent Hurtada-Sadowski changed the chart order for patient J.B. even though she knew or should have known to contact Payne about the incomplete chart order when she received conflicting information from the hospital computer system. Respondent Hurtada-Sadowski's conduct was unprofessional because she failed to confer with patient J.B.'s health care provider regarding the incomplete chart order. Having failed to confer directly with a patient's health care provider and changing the chart order of the patient's health care provider, Respondent Hurtada-Sadowski performed her duties in an incompetent, unskillful or negligent manner.

30. As alleged above, Respondent Summerlin Hospital's computer system would not allow Hurtada-Sadowski to release the chart order without making a change to the order.

31. As the facility at which the unprofessional conduct and violations of law alleged herein occurred, Respondent Summerlin Hospital is responsible for those violations, including all errors and omissions of Respondent Hurtada-Sadowski, Payne, and any other personnel in the course of violations of any law or regulation related to the practice of pharmacy, pursuant NAC 639.945(3). Accordingly, the Board may discipline Summerlin Hospital pursuant to NRS 639.210(4), NRS 639.255(1), NAC 639.945, and NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration of Respondents Aurelia Hurtada-Sadowski and Summerlin Hospital Medical Center.

DATED this 30th day of March 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AURELIA HURTADA-SADOWSKI, RPH, Certificate of Registration No. 15345,** **Respondent.**	**Case No. 25-209-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, June 3, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Luara Tucker at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 30th day of March 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AURELIA HURTADA-SADOWSKI, RPH, Certificate of Registration No. 15345,** **Respondent.**	**Case No. 25-209-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

Aurelia Hurtada-Sadowski, RPh

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 30th day of March 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Aurelia Hurtada-Sadowski, RPh
[redacted]
Las Vegas, NV [redacted]

Summerlin Hospital Medical Center Pharmacy
c/o Aurelia Hurtada-Sadowski, RPh
657 N. Town Center Dr
Las Vegas, NV 89144

Summerlin Hospital Medical Center Pharmacy
657 N. Town Center Dr
Las Vegas, NV 89144

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 11th day of June 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Aurelia Hurtada-Sadowski, RPh
c/o Jessica Gandy, Esq.
Peccole Professional Park
10080 West Alta Dr, Suite 200
Las Vegas, NV 89145

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **AURELIA HURTADA-SADOWSKI, RPH, Certificate of Registration No. 15345, and** **SUMMERLIN HOSPITAL MEDICAL CENTER, License No. IA02194,** **Respondents.**	**CASE NOS. 25-209-RPH-S** **25-209-PH-S** **STIPULATION AND ORDER [AURELIA HURTADA-SADOWSKI ONLY]**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, by and through counsel, Laura M. Tucker, Esq., and Aurelia Hurtada-Sadowski, RPH, Certificate of Registration No. 20104, ("Respondent"), by and through counsel, Jessica R. Gandy, Esq., hereby stipulate and agree as follows:

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent and this matter.

2. The Board's staff properly served Respondent with the Notice of Intended Action and Accusation ("Accusation") on file in this matter, together with the Statement to Respondent and Notice of Hearing.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing,

reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. For the purposes of resolving this matter, without admitting to the alleged facts or legal conclusions, Respondent acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation, *to wit*:

A. On or about May 5, 2025, Respondent received a chart that did not contain complete information as required by NAC 639.484(1)(b),(c). Respondent knew or should have known to contact the patient's health care provider about the incomplete chart order.

B. Respondent engaged in unprofessional conduct as defined in NAC 639.945 when she failed to confer directly with a patient's health care provider and changed the chart order of the patient's health care provider.

C. Having performed her duties in an incompetent, unskillful, or negligent manner, as described above, Respondent is subject to discipline pursuant to NRS 639.210(4), NRS 639.255(1), NAC 639.945, and NAC 639.955.

7. Those violations are pled with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

8. Now, therefore, to resolve the allegations stated in Count One of the Accusation without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agree to the imposition of the following penalties:

A. Respondent's certificate of registration no. 15345 shall be **SUSPENDED**; however, the suspension is **STAYED**, and Respondent shall be placed on probation for a period of one year from the effective date of this Order.

B. Respondent shall pay an administrative fine of **Five Thousand and 00/100 Dollars ($5,000.00)**, payable by *personal, business, certified or cashier's check or money order* written to the "**State of Nevada, Office of the Treasurer.**" Respondent shall remit

payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Stipulation.

C. Respondent shall pay the sum of **One Thousand Five Hundred and 00/100 Dollars ($1,500.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter. This sum shall be payable by *personal, business, certified or cashier's check or money order* written to the "**Nevada State Board of Pharmacy.**" Respondent shall remit payment in full to the Board's Reno office, located at 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada 89521, by January 15, 2027.

D. As a condition of probation, Respondent shall not engage in any conduct for which disciplinary action may be imposed pursuant to the provisions of NRS 639.210 and/or associated regulations.

Upon successful completion of the terms and conditions of probation as forth herein, Respondent's certificate of registration shall be automatically reinstated without conditions or restrictions.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 14, 2026. Respondent will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

//

//

//

//

//

//

//

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ____ day of _____ 2026.

By_____
AURELIA HURTADA-SADOWSKI, RPH
Certificate of Registration No. 15345

Signed this ____ day of _____ 2026.
Nevada State Board of Pharmacy

By_____
LAURA M. TUCKER, ESQ.
Senior General Counsel

Signed this ____ day of _____ 2026
Approved as to Form and Content:

_____
JESSICA R. GANDY, ESQ.
Hutchison & Steffen, PLLC
Attorney for Respondent Aurelia Hurtada-Sadowski

DECISION AND ORDER

As to Aurelia Hurtada-Sadowski, in Case No. 25-209-RPH-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this ____day of October 2026.

_____

Helen Park, President
Nevada State Board of Pharmacy

5Y

FILED
JUL 21 2026
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JUSTIN WAYNE MANSFIELD, MD,** **Certificate of Registration No. CS41165,** **Respondent.**	**Case No. 25-447-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this respondent and this matter because, at the time of the events alleged herein, Justin Wayne Mansfield, MD (Respondent) held a registration issued by the Board, Certificate of Registration No. CS41165.

FACTUAL ALLEGATIONS

2. Respondent is licensed by the Nevada State Board of Medical Examiners as a medical doctor.

3. Since November 6, 2025 through present, Respondent has held a certificate of registration issued by the Board pursuant to NRS 453.226. This certificate authorizes Respondent to prescribe controlled substances.

4. Respondent is also licensed as a medical doctor in Utah and has been the medical director of Physician's Choice Home & Health Hospice in Las Vegas for several years.

5. On May 6, 2021, Respondent applied for a controlled substances license with the Board. However, he did not complete the application, and his license was never issued.

6. On October 13, 2025, Respondent registered for an account for Nevada's Prescription Monitoring Program (PMP) and also applied for a second time for his controlled substances license.

7. On October 28, 2025, Board staff sent Respondent an email advising him that he needed to complete additional steps to complete the PMP registration process, and that his account would also not be active until he submitted his Nevada Drug Enforcement Agency (DEA) certificate.

8. On November 6, 2025, the Board issued Respondent his controlled substances license number and also advised him that he was not authorized to prescribe controlled substances until he submitted his Nevada DEA certificate to the Board.

9. On December 29, 2025, Respondent submitted his Nevada DEA certificate to the Board. On December 30, 2025, the Board activated Respondent's PMP account.

10. Following activation of Respondent's account, a Board investigator ran a prescriber activity report in the PMP database and found that, between January 5, 2020 and December 29, 2025, when he did not have an active controlled substances license with the Board, Respondent prescribed a total of 2,494 controlled substances to Nevada patients. Respondent prescribed the controlled substances using his Utah DEA registration number.

11. During that time, because Respondent was unable to access his PMP account, he would not have been able to run a patient activity report before prescribing, and he would not have been able to run a report to review his own prescribing activity.

12. A Board investigator ran a prescriber activity report and a patient request history for a date range of December 29, 2025 and March 17, 2026 and found that Respondent wrote one hundred sixty-nine (169) unique controlled substances prescriptions for seventy-seven (77) patients. Respondent did not run a patient activity report for any of the patients. Respondent has run a report to review his own prescribing activity every work day since he has obtained his license.

\\\

APPLICABLE LAW

13. In Nevada, it is unlawful to dispense a controlled substance except as authorized by NRS Chapter 453. NRS 453.321(1)(a). "Dispense" is defined to include the act of prescribing a controlled substance. NRS 453.056.

14. Every practitioner who intends to prescribe controlled substances in Nevada must first apply for and obtain a certificate of registration from the Board. NRS 453.226(1); NRS 453.231(3). The practitioner must renew the certificate of registration on a biennial basis. *Id.* A practitioner who fails to register or renew may be subject to criminal and/or civil penalties for prescribing controlled substances without a certificate of registration. NRS 453.232; NRS 453.553; NRS 453.5531.

15. It is unlawful for any person to sell or dispense a prescription drug unless the person holds the appropriate certificate, license required pursuant to Chapter 639, Chapter 453, or Chapter 454 of NRS, as applicable, authorizing the person to take such action, and complies with the regulations adopted by the Board. NRS 639.100(1).

16. A practitioner may not prescribe controlled substances until his or her application is granted and a certificate of registration is issued to the person by the Board and unless he or she is registered with the DEA to dispense controlled substances in Nevada and has provided a copy of that registration to the Board. *See* NAC 453.210(1), *as amended* by LCB File No. R197-22 (effective February 27, 2024).

17. When a practitioner first obtains a certificate of registration to prescribe controlled substances, the practitioner must enroll in the PMP and complete a course of instruction concerning the use of the PMP database. NRS 453.164(5) & (6); NAC 453.065.

18. A practitioner shall, before issuing an initial prescription for a controlled substance, and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance, obtain a patient utilization report regarding the patient from the PMP. NRS 639.23507.

19. A practitioner registered with the Board to write prescriptions for controlled substances must access his or her prescriber activity in the PMP at least once every 6 months to review prescriptions issued by the practitioner and to verify for the Board that he or she continues to have access to the PMP. *See* NRS 453.164(7) and NRS 639.23507.

20. The Board may revoke or suspend the registration of any practitioner who has violated any Nevada statute or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. NRS 639.210(12).

21. The Board may revoke or suspend the existing registration of any practitioner who has engaged in unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4).

22. A practitioner's conduct is deemed unprofessional and/or contrary to the public interest if the practitioner performs his or her duties in an incompetent, unskillful, or negligent manner. NAC 639.945(1)(i).

23. Unprofessional conduct includes performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration. NAC 639.945(1)(k).

24. The Board may suspend or revoke a registrant's controlled substances registration if a registrant has violated any provision of NRS 453.162 to 453.165, inclusive, or 639.23507, or committed an act that would render registration inconsistent with the public interest as determined pursuant to that section. *See also* NRS 453.241(1).

25. In addition to or in lieu of revoking or suspending a practitioner's certificate of registration due to any violation described herein, the Board may impose an administrative fine upon the practitioner. The fine may not exceed $10,000 for each offense. NRS 639.255(1)(f) and (3).

\\\

\\\

COUNT ONE

Unprofessional Conduct/Conduct Contrary to the Public Interest - Noncompliance with Prescription Monitoring Program

26. As alleged above, between January 5, 2020 and December 29, 2025, Respondent failed to query the PMP database regarding his own prescriber activity. The PMP database compiles a report of prescribing activity for any practitioner who makes such a query. This allows the practitioner to evaluate whether anyone has fraudulently used the practitioner's credentials to prescribe controlled substances.

27. As alleged above, between January 5, 2020 and the present, Respondent failed to query the PMP database regarding the patient utilization report before issuing an initial prescription for a controlled substance, and at least once every 90 days thereafter for the duration of the course of treatment using the controlled substance.

28. By failing to review his own prescriber activity on a semi-annual basis, as required by NRS 453.164(7) and NRS 639.23507, and failing to review the patient utilization report prior to issuing an initial prescription, as required by NRS 639.23507, Respondent performed his duties as the holder of a certificate issued by the Board in an incompetent, unskillful or negligent manner. This violation of law renders his Nevada controlled substance registration inconsistent with the public interest.

29. As alleged above, Respondent's conduct constitutes unprofessional conduct for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 639.255(3), NAC 639.945(1)(i), NRS 453.236(1)(d) and (e), and NRS 453.241(1).

\\\

\\\

\\\

\\\

\\\

\\\

COUNT TWO

Violation of State Law – Performing an Act, Task or Operation for Which Licensure is Required without the Required License

30. As alleged above, between January 5, 2020 and December 29, 2025, Respondent engaged in unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(k) when he prescribed controlled substances without a license as required by NRS 453.226(1); NRS 453.231(3); and NRS 639.100(1). *See also* NAC 639.945(1)(k).

31. This is a violation of law for which the Board may impose administrative discipline. See NRS 639.210(4) and (12); NRS 453.236(1)(e); NRS 453.231(1)(h).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Justin Wade Mansfield.

DATED this 21st day of JULY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JUSTIN WAYNE MANSFIELD, MD,** **Certificate of Registration No. CS41165,** **Respondent.**	**Case No. 25-447-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 21st day of JULY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JUSTIN WAYNE MANSFIELD, MD,** **Certificate of Registration No. CS41165,** **Respondent.**	**Case No. 25-447-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

JUSTIN WAYNE MANSFIELD, MD

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 21st day of July 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Justin Wayne Mansfield, MD
[redacted]
Farmington, UT [redacted]

Justin Wayne Mansfield, MD
c/o Physicians Choice Home Health & Hospice
6720 Via Austi Pkwy, Suite 250
Las Vegas, NV 89119

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JUSTIN WADE MANSFIELD, MD,** **Certificate of Registration No. CS41165,** **Respondent.**	**Case No. 25-447-CS-S** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through Senior General Counsel Laura M. Tucker, Esq., and Respondent Justin Wade Mansfield, M.D. (Respondent), Certificate of Registration No. CS41165, by and through counsel, W. Michael Black, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. On or about July 25, 2026, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. On or about August 5, 2026, the Board's General Counsel and Respondent's Counsel agreed to a stay of the deadline for Respondent to file an Answer and Notice of Defense to the Accusation.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing,

reconsideration, appeal and any and all other rights related to this action that may be accorded by the Nevada Administrative Procedure Act, Administrative Procedure Before Certain Regulatory Bodies, and the Nevada Pharmacy Act.

6. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit*:

A. On May 6, 2021, Respondent applied for a controlled substances license with the Board. However, he did not complete the application, and his license was never issued.

B. On October 13, 2025, Respondent registered for an account for Nevada's Prescription Monitoring Program (PMP) and also applied for a second time for his controlled substances license.

C. On November 6, 2025, the Board issued Respondent his controlled substances license number and also advised him that he was not authorized to prescribe controlled substances until he submitted his Nevada DEA certificate to the Board.

D. On December 29, 2025, Respondent submitted his Nevada DEA certificate to the Board. On December 30, 2025, the Board activated Respondent's PMP account.

E. Following activation of Respondent's account, a Board investigator ran a prescriber activity report in the PMP database and found that, between January 5, 2020 and December 29, 2025, when he did not have an active controlled substances license with the Board, Respondent prescribed a total of 2,494 controlled substances to Nevada patients. Respondent prescribed the controlled substances using his Utah DEA registration number.

F. A Board investigator ran a prescriber activity report and a patient request history for a date range of December 29, 2025 and March 17, 2026 and found that Respondent wrote one hundred sixty-nine (169) unique controlled substances prescriptions for seventy-seven (77) patients. Respondent did not run a patient activity report for any of the

patients. Respondent has run a report to review his own prescribing activity every work day since he has obtained his license.

G. By failing to review his own prescriber activity on a semi-annual basis, as required by NRS 453.164(7) and NRS 639.23507, and failing to review the patient utilization report prior to issuing an initial prescription, as required by NRS 639.23507, Respondent performed his duties as the holder of a certificate issued by the Board in an incompetent, unskillful or negligent manner. This violation of law renders his Nevada controlled substance registration inconsistent with the public interest. Respondent's conduct constitutes unprofessional conduct for which the Board may impose administrative discipline. NRS 639.210(4) and (12); NRS 639.255(3), NAC 639.945(1)(i), NRS 453.236(1)(d) and (e), and NRS 453.241(1).

H. Between January 5, 2020 and December 29, 2025, Respondent engaged in unprofessional conduct or conduct contrary to the public interest as defined in NAC 639.945(1)(k) when he prescribed controlled substances without a license as required by NRS 453.226(1); NRS 453.231(3); and NRS 639.100(1). *See also* NAC 639.945(1)(k). This is a violation of law for which the Board may impose administrative discipline. See NRS 639.210(4) and (12); NRS 453.236(1)(e); NRS 453.231(1)(h).

7. Those violations are pled with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

8. To resolve this matter without incurring any further costs or the expenses associated with a hearing, the Board and Respondent agrees to the imposition of the following penalties:

A. Respondent shall pay a fine of **Six Thousand Dollars ($6,000.00)** for the alleged violations, payable by *cashier's check* or *check* or *money order* made payable to **"State of Nevada, Office of the Treasurer,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Order;

B. Respondent shall pay **One Thousand Dollars ($1,000.00)** to partially reimburse the Board for recoverable attorney's fees and costs incurred in investigating and prosecuting this matter, payable by *cashier's check* or *check* or *money order* made payable to **"Nevada State Board of Pharmacy,"** to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within thirty (30) days of the effective date of this Order;

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on October 14, 2026. Respondent will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release each other from any and all additional claims arising from the facts set forth in the Accusation

on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and has freely and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of _____, 2026

JUSTIN WADE MANSFIELD, MD,
Certificate of Registration No. CS41165

Signed this ___ day of _____, 2026

LAURA M. TUCKER
Senior General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this ___ day of _____, 2026

W. MICHAEL BLACK, ESQ.
Attorney for Respondent Justin Wade Mansfield, MD

DECISION AND ORDER

As to Justin Wade Mansfield, MD, in Case No. 25-447-CS-S, the Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as its final decision in the matter and hereby orders that the terms of the foregoing Stipulation be made effective upon the date of entry set forth below.

IT IS SO ORDERED.

Entered this ____day of October 2026.

_____

Helen Park, President
Nevada State Board of Pharmacy

5Z

FILED
SEP 09 2026
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **VITA PHARMACY 2,** **License No. PH04645,** **Respondent.**	**CASE NO. 26-344-PH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and/or NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and this respondent because, at the time of the events alleged herein, Respondent Vita Pharmacy 2, License No. PH04645 (Vita 2), located at 1807 W. Charleston Blvd., Suite 110 in Las Vegas, Nevada, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. On or about March 28, 2024, George and Janice Gange submitted an application to operate a pharmacy in Nevada (2024 Application) under the business name District Pharmacy. The 2024 Application identified District Pharmacy Corporation as the owner. The application was approved in September 2024.

3. The 2024 Application identified George Gange as the President and Janice Gange as the managing pharmacist of District Pharmacy.

4. In an action unrelated to District Pharmacy, on or about February 6, 2026, the Board issued a citation-and-fine-order (February Citation) to Ramy Massoud (Massoud) for

unlicensed business activity related to his ownership of Lyfe Pharmacy, located at 9280 W. Sunset Road, Suite 230, Las Vegas, Nevada. Specifically, the Board cited Massoud for operating Lyfe Pharmacy without approval from the Board as a new owner. Massoud subsequently paid the citation.

5. On or about March 5, 2026, Massoud submitted a new pharmacy ownership and name change application for Lyfe Pharmacy, under the new name Vita Pharmacy. In the application, he disclosed the February Citation. The Board approved Vita Pharmacy's license on April 2, 2026, under License No. PH04799.

6. On March 16, 2026, the Board received a letter from Massoud indicating a "fractional change in beneficial ownership" of District Pharmacy. The letter indicated the following ownership structure:

- George Gange, 50 percent ownership;
- Ramy Massoud, 45 percent ownership; and
- Janice Gange, 5 percent ownership.

7. In June 2026, the Board received a change of ownership and name change application for District Pharmacy (June 2026 Application). The application listed Massoud as 100 percent owner and changed the name to Vita Pharmacy 2 (Vita 2).

8. On the Vita 2 application, Massoud did not disclose the February Citation. Specifically, on page 3, Section 3: History of the Company of the June 2026 Application, Massoud marked "No" in response to the question "Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?"

9. In addition, in Section 7 of the Personal History Application section of the June 2026 Application, Massoud failed to disclose to the Board his ownership of Vita Pharmacy and Lyfe Pharmacy.

10. Massoud signed and dated the application, acknowledging that the information was true and correct and that making any false representation in the application is a crime pursuant to NRS 639.281.

11. The Board approved Vita 2's application as part of the Board's consent agenda during the July 15, 2026 meeting, and Vita 2 was issued License No. PH004645 on July 16, 2026.

12. On or about August 5, 2026, a Board Investigator recognized that the Board had granted Vita 2's name change and change of ownership application with Massoud as the owner. Upon review of Vita 2's application, the Board Investigator noted the Massoud failed to disclose the February Citation and ownership of Vita Pharmacy.

13. On or about August 11, 2026, the Board issued a cease-and-desist to Vita 2 and Massoud ordering Vita 2 to discontinue operations with Massoud as owner. On August 14, 2026, after further discussion with Board staff, the Board permitted Massoud to continue acting as owner with additional monitoring requirements.

APPLICABLE LAW

14. An applicant to operate a pharmacy or outsourcing facility must submit a complete and accurate application. NAC 639.500(2); NAC 639.6915(1).

15. It is unlawful for a person knowingly or intentionally to furnish false or fraudulent material information in, or omit any material information from, any application for registration under NRS Chapter 639. NRS 639.281(1).

16. Willfully making a materially false statement or falsifying records to the Board is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(9).

17. Obtaining any registration by the filing of an application, or any record, affidavit or other information in support thereof, which is false or fraudulent, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(10).

18. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

19. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE
Furnishing False Material Information to Board/
Violations of State Law/Unprofessional Conduct

20. As alleged above, Vita 2, by and through its owner Massoud, misrepresented and/or failed to fully disclose information material to its application as to the February Citation and Massoud's other pharmacy ownership interests.

21. Pursuant to Nevada law, Vita 2 had a duty to submit a complete and accurate application to the Board. NAC 639.500(2); NAC 639.6915(1).

22. In misrepresenting and/or failing to disclosed information on its application pursuant to Nevada law, Vita 2 breached its duty and violated NRS 639.281(1), and is therefore subject to discipline pursuant to NRS 639.210(9) and/or (12).

COUNT TWO
Obtaining Registration by False or Fraudulent Application

23. As alleged above, Vita 2, by and through its owner Massoud, misrepresented and/or failed to fully disclose information material to its application as to the February Citation and Massoud's other pharmacy ownership interests when obtaining a change of ownership and name change for License No. PH04645.

24. By obtaining a license by filing an application in support thereof that is false or fraudulent, Vita 2 is therefore subject to discipline pursuant to NRS 639.210(10).

\\

\\

\\

COUNT THREE

Pharmacy/Pharmacy Owner Responsibility

25. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Vita 2 is responsible for those violations, including all errors and omissions of Massoud or any other owners and/or officers, pursuant to NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this respondent.

DATED this 9th day of SEPTEMBER 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **VITA PHARMACY 2,** **License No. PH04645,** **Respondent.**	**Case No. 26-344-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, October 14, 2026, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney, Laura Tucker, at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of SEPTEMBER 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **VITA PHARMACY 2,** **License No. PH04645,** **Respondent.**	**Case No. 26-344-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2026.

_____

AUTHORIZED REPRESENTATIVE FOR VITA PHARMACY 2

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of September 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Vita Pharmacy 2
1807 W Charleston Blvd, Suite 110
Las Vegas, NV 89102

William J. Stilling, Esq.
222 South Main St, Suite 500
Salt Lake City, UT 84101

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

6

6A

FILED
MAY 29 2026
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DAVID LINDBERG,** **Respondent.**	**CASE NO. 24-482-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.2895 and NRS 233B.121-.126, *inclusive*, on or about February 11, 2026, a Citation and Fine Order was served upon Respondent David Lindberg (Respondent), former owner/operator of D.C.L., LLC, dba Magnus Medical Health and Wellness (Magnus), alleging violations of Nevada law as set forth herein.

FACTUAL ALLEGATIONS

1. On or about March 2022, Respondent began operating the wellness clinic Magnus, located at 8540 S. Eastern Avenue, Suite 160, in Las Vegas, Nevada. Respondent is not a licensed practitioner as that term is defined at NRS 453.126(1) and 639.0125(1) and not licensed by the Board or the Federal Drug Enforcement Administration (DEA) to possess, administer, prescribe or dispense dangerous drugs or controlled substances.

2. During the relevant timeframe, Justin Spangler, PA (Spangler), Mikayla Strief, APRN (Strief), Mary Miller-Wilson, APRN (Miller-Wilson), Daniel Inglish, DO (Inglish), and Tiana Hubbard, APRN (Hubbard) worked as practitioners at Magnus. Each of the practitioners were licensed by the Board to prescribe controlled substances.

3. On or about September 2024, Respondent sold Magnus to new owners Donald Min (Min) and Young Kim (Kim), who renamed the business Young4Life. Neither Min nor Kim are licensed practitioners as that term is defined at NRS 453.126(1) and 639.0125(1) or licensed by the Board or DEA to possess, administer, prescribe or dispense dangerous drugs or controlled substances.

4. Min and Kim formed Young4Life in late 2024 and assumed Magnus's established customers and business model. Young4Life retained Respondent as a marketing consultant.

5. During the relevant timeframe, Spangler and Mark Bernardi, MD (Bernardi) worked as practitioners at Young4Life. Both were licensed by the Board to prescribe controlled substances.

6. A Board investigation found that, as owner of Magnus, between September 2022 and September 2024, Respondent regularly used several Magnus employees' prescribing credentials to issue prescriptions and access prescribing systems. From September 2024 through at least May 2025, as marketing consultant, Respondent continued using Young4Life employees' prescribing credentials to issue prescriptions and access prescribing systems.

7. Specifically, during the relevant timeframe, each Magnus and/or Young4Life employee practitioner permitted Respondent to access prescribing systems and issue the following controlled substance prescriptions using their electronic prescribing credentials:

a. According to Board records, between May 2024 and November 2024, while employed by Magnus and Young4Life, Spangler authorized 548 controlled substance prescriptions for 397 unique patients. According to a Board investigation, at least some of these prescriptions were actually issued by Respondent using Spangler's credentials without Spangler's knowledge.

b. Between May 2024 and November 2024, while employed by Magnus, Strief authorized 170 controlled substance prescriptions for Nevada patients. According to a Board investigation, at least some of these prescriptions were actually issued by Respondent using Strief's credentials without Strief's knowledge.

c. Per company policy, Strief delegated the entire prescribing process to Magnus. As such, Strief sent her prescribing token to Magnus and did not personally authorize any prescriptions for armodafinil, chorionic gonad or ketamine that appeared on her prescribing report from April to November 2024.

d. Between May 2024 and May 2025, while employed by Magnus, Inglish prescribed 63 controlled substances for Nevada patients. According to a Board investigation, at least some of these prescriptions were actually issued by Respondent using Inglish's credentials without Inglish's knowledge.

e. Between March 2022 and March 2024, while employed by Magnus, Miller-Wilson prescribed 1,846 controlled substances for 714 unique Nevada patients. According to a Board investigation, at least some of these prescriptions were actually issued by Respondent using Miller-Wilson's credentials without Miller-Wilson's knowledge.

f. Per company policy, Miller-Wilson delegated the entire prescribing process to Magnus.

g. Between February 2025 and June 25, 2025, while employed by Young4Life, Bernardi prescribed 327 controlled substances for 203 unique Nevada patients. According to a Board investigation, at least some of these prescriptions were

actually issued by Respondent using Bernardi's credentials without Bernardi's knowledge.

h. Between February 2023 and March 2024, while employed by Magnus, Hubbard prescribed 381 controlled substances for 202 unique Nevada patients. According to a Board investigation, at least some of these prescriptions were actually issued by Respondent using Hubbard's credentials without Hubbard's knowledge.

8. During the relevant timeframe, Respondent also used the prescribing credentials of at least two additional medical professionals who did not hold licenses with the Board to prescribe controlled substances. Specifically, the following unlicensed prescribers permitted Respondent to access prescribing systems and issue the following controlled substance prescriptions using their electronic prescribing credentials:

a. While employed by Magnus and/or Young4Life between November 2024 and May 2025, Paul Branch, MD, (Branch) a doctor who does not hold a license with the Board, prescribed 384 controlled substance prescriptions for 268 unique Nevada patients. According to a Board investigation, at least some of these prescriptions were actually issued by Respondent using Branch's credentials without Branch's knowledge.

b. While employed by Magnus and/or Young4Life on or about May 2024, Juanita Golden-Allen, APRN, who does not hold a license with the Board, prescribed 128 controlled substance prescriptions for 99 unique Nevada patients. According to a Board investigation, at least some of these prescriptions were actually issued by Respondent using Golden-Allen's credentials without Golden-Allen's knowledge.

9. In answer to a Board investigator's questions, some of the practitioners denied having issued any prescriptions for controlled substances.

10. On or about March 9, 2026, Respondent appealed the Citation and Fine and requested a hearing before the Board.

APPLICABLE LAW

11. Pursuant to NRS 639.100(1), it is unlawful for any person to manufacture, engage in wholesale distribution, compound, sell or dispense, or permit to be manufactured, distributed at wholesale, compounded, sold or dispensed, any drug, poison, medicine or chemical, or to dispense or compound, or permit to be dispensed or compounded drugs without having secured the appropriate license and/or certificate of registration from the Board.

12. Only a practitioner as defined in NRS 453.126 who holds a certificate of registration from the Board may compound, furnish, and/or administer a controlled substance in Nevada. NRS 453.226.

13. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession, to a patient with whom the practitioner has established a bona fide therapeutic relationship. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a); 21 CFR § 1306.04(a); NRS 453.381(1); NRS 639.235(1); NRS 639.23911(1)(a); NRS 639.2813(1).

14. A practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor, or biometric information, with any other person. The practitioner must not allow any other person to use the token or enter the knowledge

factor or other identification means to sign prescriptions for controlled substances. 21 CFR § 1311.102 and NAC 639.7105(2)(b).

COUNT ONE
Violations of State Law – Unlawful Prescribing of Controlled Substances

15. As alleged above, Respondent is not a licensed practitioner as that term is defined at NRS 453.126(1) and 639.0125(1) and not licensed by the Board pursuant to NRS 453.226 or the DEA to possess, administer, prescribe or dispense dangerous drugs or controlled substances.

16. As alleged above, by using the credentials of at least six licensed practitioners and at least two unlicensed practitioners and acting under their authority without their express knowledge or authorization to fraudulently issue prescriptions for controlled substances, Respondent violated NRS 639.100(1).

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 639.2895(2). You have the right to a hearing before the Board to answer the allegations and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. **The Board has scheduled your hearing on this matter for Wednesday, July 15, 2026, at 9:00 a.m. or soon thereafter. The hearing will occur at Hilton Garden Inn Las Vegas Strip South - 7830 S. Las Vegas Blvd, Las Vegas, NV 89123.**

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the

Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

Signed this 29th day of MAY 2026.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 29th day of May 2026, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

David Lindberg
c/o Magnus Health/Medical
[redacted]
Las Vegas, NV [redacted]

David Lindberg
c/o Jeff Setness, Esq.
2275 Corporate Circle, Suite 220
Henderson, NV 89074

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

JOE LOMBARDO
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA
BOARD OF PHARMACY
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

February 11, 2026

Via Certified/Regular U.S. Mail
David Lindberg
c/o Jeff Setness, Esq.
2275 Corporate Circle, Suite 220
Henderson, NV 89074

9489 0178 9820 3042 2842 04

David Lindberg, Owner
Magnus Health/Medical
[redacted]
Las Vegas, NV [redacted]

9489 0178 9820 3042 2842 11

Re: CITATION & FINE: Case No. 24-482-A-S, Unlicensed Prescribing; Accessing Prescribing Systems and Prescribing Prescriptions without Authority

Dear Mr. Lindberg:

The Nevada State Board of Pharmacy (Board) has determined that you, along with your company, Magnus Health/Medical (Magnus), previously located at 8540 S. Eastern Avenue, Suite 160 in Las Vegas, engaged in unlicensed practice related to prescribing controlled substances and accessing prescribing systems without authority in violation of Nevada law. Furthermore, the Board has determined that you continued this conduct as an employee of Young4Life after selling Magnus Health to new owners.

Specifically, the Board found that between September 2022 and May 2025, you regularly used at least eight practitioners' credentials at both Magnus and Young4Life to issue prescriptions and access the prescribing systems without authority. You are not a licensed prescriber with the DEA or the Board.

Under NRS 639.100(1), it is unlawful to purchase, receive, store, possess and/or sell dangerous drugs or controlled substances without having secured the appropriate certificate, license, or permit issued by the Board. In Nevada, a prescription for a controlled substance may be issued only for a legitimate medical purpose and in the usual course of his or her professional practice by an individual practitioner who holds a DEA registration and is authorized by the Board to

prescribe controlled substances, to a patient with whom the practitioner has established a bona fide therapeutic relationship. *See* 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR § 1306.03(a); 21 CFR § 1306.04(a); NRS 453.381(1); NRS 639.235(1); NRS 639.23911(1)(a). An electronic prescription for a controlled substance must be issued in compliance with 21 CFR § 1311.100, NRS 453.385, NRS 639.23535, and NAC 639.7105(2). Furthermore, a practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor, or biometric information, with any other person, and must not allow any other person to use the token or enter the knowledge factor or other identification means to sign prescriptions for controlled substances. 21 CFR § 1311.102.

Accordingly, by accessing the prescribing system and prescribing drugs using at least eight practitioners' credentials and without a license, you have engaged in unlicensed practice related to controlled substances in violation of Nevada law. This letter shall serve as a **CITATION** pursuant to NRS 639.2895(2) for your unlicensed activity and unlawful use of prescribing credentials. Pursuant to NRS 639.2895(3), the Board has assessed an administrative fine against you in the amount of Five Thousand Dollars ($5,000.00) with respect to each of the eight known practitioners whose credentials you used as a means of accessing prescribing systems and issuing prescriptions without lawful authority. The aggregate fine is **Forty Thousand Dollars** ($40,000.00), payable in accordance with the paragraphs below.

You have the right to appeal this citation by submitting a written request for a hearing to the Board at the Board's Reno office no later than 30 days after receipt of this citation. NRS 639.2895(2). Unless you submit a timely appeal, the above fine must be paid within the same time frame. Payment must be tendered in the form of a certified check, cashier's check or money order made payable to "**State of Nevada, Office of the Treasurer**." Please remit payment to the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521.

If you fail to timely pay the above fine or appeal this citation, as applicable, the Board may take further action, including referral to the Nevada Controller's Office for collection. See NRS 353C.195; 45 CFR §§ 60.3, 60.5. Pursuant to the Nevada Public Records Act, this letter constitutes a public record that must be released to anyone who makes a proper request for it. If you have any questions concerning this citation or your right to appeal the above finding, you may contact the Board's General Counsel Laura Tucker at 702-486-6420, ext. 128, or *via* email at l.tucker@pharmacy.nv.gov.

Sincerely,

The Nevada State Board of Pharmacy

7

7A & 7B

From: LAUGHLIN PHARMACY
To: Board Coordination
Cc: David Wuest
Subject: Request for Board Hearing - Medicaid Access Concerns
Date: Wednesday, September 16, 2026 9:28:25 AM

You don't often get email from ymwell2022@gmail.com. Learn why this is important

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Dear Nevada State Board of Pharmacy,

I am writing to respectfully request a hearing before the Nevada State Board of Pharmacy at a future Board meeting for consideration of the early termination of probation associated with my pharmacist registration and pharmacy license.

A significant reason for this request is an issue involving access to Medicaid pharmacy services in the Laughlin community. Express Scripts has advised that my pharmacy cannot participate in its provider network while the applicable license remains under active probation. As a result, the probationary status is creating a barrier to our ability to participate as a provider and serve MCO Medicaid patients in our community.

This issue has implications beyond my individual licensure. Laughlin is a geographically isolated community, and access to local pharmacy services is important to its residents, particularly Medicaid patients who may have limited transportation or difficulty obtaining their medications elsewhere.

For this reason, I respectfully request an opportunity to appear before the Board and present the circumstances supporting early termination of probation, and the effect that the continued probationary status is having on our ability to provide pharmacy services to Medicaid patients in Laughlin.

Kathy Ochs, Vice President of the Laughlin Town Advisory Board, would also like to attend the hearing with me and speak on behalf of Laughlin residents and the local community regarding the need for pharmacy access and the impact this situation is having on the community.

If permitted under the Board's procedures, we respectfully request that this matter be placed on the agenda for a future Board meeting.

Please advise me of the appropriate procedure for requesting this hearing, including any petition, supporting documentation, or other materials that must be submitted, applicable deadlines, and whether Ms. Ochs may appear and provide comments or testimony to the Board.

Thank you for your time and consideration.

Sincerely,

Laughlin Pharmacy (License # PH04520) (Case # 24-289-PH-S)

Youjin Seo (License#18704) (Case #24-289-RPH-A-S)

Youjin (Rachel) Seo, Pharm.D
Pharmacist / Owner

Laughlin Pharmacy
3080 S Needles Hwy, Ste 1800, Laughlin, NV 89029
Phone: (702) 709-5300 | Fax: (702) 709-5303

Docusign Envelope ID: 8E3B9256-C1F5-462A-9F6A-E8A9D329995D

FILED
DEC 04 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LAUGHLIN PHARMACY & WELLNESS CENTER, Pharmacy License No. PH04520,** **YOUJIN SEO, RPH, Certificate of Registration No. 18704, and** **THU VO, RPH, Certificate of Registration No. 18661,** **Respondents.**	**CASE NOS. 24-289-PH-S** **24-289-RPH-A-S** **24-289-RPH-B-S** **STIPULATION AND ORDER [RESPONDENTS LAUGHLIN PHARMACY AND SEO ONLY]**

J. David Wuest, in his capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondents Youjin Seo, RPh (Seo), Certificate of Registration No. 18704, and Laughlin Pharmacy & Wellness Center (Laughlin Pharmacy), Pharmacy License No. PH04520, by and through counsel, Michael M. Lin, Esq., **HEREBY STIPULATE AND AGREE THAT**:

1. The Board has jurisdiction over Respondents and this matter.

2. On or about October 21, 2024, Respondent were served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

3. On or about November 18, 2024, Respondents each filed an Answer and Notice of Defense to the Accusation.

Docusign Envelope ID: 8E3B9256-C1F5-462A-9F8A-E8A9D329995D

4. Respondents are fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

5. Respondents are aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to them pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that either Respondent has failed to comply with the provisions of this Stipulation, Respondents hereby knowingly and voluntarily waive their rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to them by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

7. Respondents do not contest the allegations in the Accusation, but acknowledge that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that:

A. Seo, as co-owner and a staff pharmacist at Laughlin Pharmacy, together with Respondent Thu Vo, RPh (Vo), Certificate of Registration No. 18661, as managing pharmacist, dispensed adulterated and/or misbranded sterile drug products that were not compounded in compliance with NAC 639.6701-.6702, *inclusive*, NAC 639.6705 -.67079, *inclusive*, and related federal law, 21 USC § 353a and USP-797 standards, in further violation of 21 USC § 331(a), (b) and/or (c), NRS 454.351(1), NRS 585.520(1) and (2), NRS 639.100(1) and/or NRS 639.286;

Docusign Envelope ID: 8E3B9256-C1F5-462A-9F6A-E8A9D329995D

B. Seo and Vo directly administered compounded drug products to patients in violation of NRS 454.213;

C. Seo, Vo and Laughlin Pharmacy failed to keep and maintain complete, accurate and readily retrievable records accounting for all dangerous drugs in violation of NRS 454.286, NRS 454.291, NAC 639.487(2) and/or NAC 639.510(2)(b);

D. Seo engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(a) and (i); and

E. As the pharmacy/pharmacy owner at which the violations alleged herein occurred, Seo and Laughlin Pharmacy are responsible for those violations, including all errors and omissions of the pharmacy personnel, and subject to discipline pursuant to pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

8. Those violations are pled with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

9. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Youjin Seo, RPh, Certificate of Registration No. 18704, stipulate to the following penalties. The certificate of registration of Respondent Youjin Seo, RPh (Seo), Certificate of Registration No. 18704, is revoked pursuant to NRS 639.255(1)(d); the revocation is stayed, and Respondent is placed on probation for a period of five (5) years pursuant to NRS 639.255(1)(b) subject to the following conditions:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Seo shall pay a fine of Five Thousand Dollars ($5,000.00) for the violations, by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by April 1, 2025;

Docusign Envelope ID: 8E3B9256-C1F5-462A-9F6A-E8A9D329995D

B. Pursuant to NRS 622.400, Seo shall pay Two Thousand Dollars ($2,000.00) to partially reimburse the Board for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by April 1, 2025;

C. Beginning sixty (60) days after the effective date of this Order, Seo shall not work as managing pharmacist of any pharmacy licensed by the Board for the remainder of probation;

D. Seo shall not engage in the practice of compounding sterile drug products for one (1) year from the effective date of this Order, and shall complete twenty (20) extra hours of continuing education (CE) on sterile compounding by the biennial registration renewal date of October 31, 2025, in addition to the CE hours she must otherwise complete to maintain licensure, and provides certificates demonstrating completion to the Board;

E. Seo shall not engage in the practice of compounding nonsterile drug products unless and until she completes ten (10) extra hours of continuing education (CE) on nonsterile compounding, in addition to the CE hours she must otherwise complete to maintain licensure, and provide certificates demonstrating completion to the Board; and

F. Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against her while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. 18704 will be fully restored.

10. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Laughlin Pharmacy & Wellness Center, Pharmacy License No. PH04520, stipulate to the following penalties. The pharmacy license of Respondent Laughlin Pharmacy & Wellness Center, Pharmacy License No. PH04520, is revoked pursuant to NRS 639.255(1)(d); the revocation is stayed, and Respondent is placed on probation for a period of three (3) years pursuant to NRS 639.255(1)(b subject to the following conditions:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Laughlin Pharmacy shall pay a fine of Twelve Thousand Dollars ($12,000.00) for the violations by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by April 1, 2025;

B. Pursuant to NRS 622.400, Laughlin Pharmacy shall pay Two Thousand Dollars ($2,000.00) for partially reimburse the Board for recoverable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by April 1, 2025;

C. Prior to compounding sterile drug products, Laughlin Pharmacy shall comply with the following requirements:

(i) Consistent with NAC 639.67013, the managing pharmacist and a designated person (technician) shall complete the USP Implementation Training, CORE Compounding Training and Sterility Assurance Training courses through accredited vendor PCCA; training will take place onsite and online

Docusign Envelope ID: 8E3B9256-C1F5-462A-9F6A-E8A9D329995D

at https://www.pccarx.com/PCCAEducation/Pharmacy. Documentation of successful completion shall be provided to Board staff.

(ii) Consistent with NAC 639.67013, the managing pharmacist and a designated person (technician) shall complete all modules comprising the Sterile Compounding Training Schedule through Critical Point at https://www.criticalpoint-lms.com. Documentation of successful completion shall be provided to Board staff.

(iii) Upon completion of items (i) and (ii), Laughlin Pharmacy shall be subject to inspection by Board staff pursuant to NRS 639.090 and NRS 639.289.

Upon resuming the compounding of sterile drug products, Laughlin Pharmacy shall comply with the following requirements:

(iv) Consistent with NAC 639.67013, each pharmacist and pharmaceutical technician shall complete the training specified in items (i) and (ii) prior to engaging in the practice of compounding sterile drug products.

(v) Laughlin Pharmacy shall undergo at least two (2) inspections by the National Association of Boards of Pharmacy (NABP) during the probation period, with all findings provided directly to Board staff.

D. Board inspectors shall conduct quarterly inspections of Laughlin Pharmacy for the probation period, and Respondent shall bear and reimburse the Board for inspection costs in an amount not to exceed $500 per quarterly inspection;

E. Laughlin Pharmacy shall establish and put into practice all necessary policies and procedures for compounding and dispensing drug products in conformance with federal and state law; and

F. Respondent shall have no new charges filed against Laughlin Pharmacy while on probation.

Docusign Envelope ID: 8E3B9256-C1F5-462A-9F6A-E8A9D329995D

Upon successful completion of probation, Respondent's License No. PH04520 will be fully restored.

11. Any failure by either Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing the non-compliant Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by the non-compliant Respondent, the Board may lift the stay and immediately revoke the certification or registration or pharmacy license of the non-compliant Respondent, as applicable, and impose additional discipline upon that Respondent not inconsistent with the provisions of NRS Chapter 639.

12. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on December 4, 2024. Respondents will appear at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondents or counsel are not present at the meeting.

13. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

14. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

Docusign Envelope ID: 8E3B9256-C1F5-462A-9F6A-E8A9D329995D

Respondents have fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

12/4/2024 | 2:04:05 PM PST
Signed this ___ day of _____ 2024

DocuSigned by:

LAUGHLIN PHARMACY & WELLNESS CENTER
Pharmacy License No. PH04520

12/4/2024 | 2:04:05 PM PST
Signed this ___ day of _____ 2024

DocuSigned by:

YOUJIN SEO, RPH
Certificate of Registration No. 18704

APPROVED AS TO FORM AND CONTENT
12/4/2024 | 1:58:19 PM PST
this ___ day of DS **2024**

DocuSigned by:

MICHAEL M. LIN, ESQ.
Counsel for Respondents

Signed this 4TH **day of** DECEMBER **2024**

BRETT KANDT
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Youjin Seo, RPh, Certificate of Registration No. 18704, and Respondent Laughlin Pharmacy & Wellness Center, Pharmacy License No. PH04520, in Case Nos. 24-289-PH-S and 24-289-RPH-A-S, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.
Entered this 4th day of December 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 6th day of Dec. 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Michael M. Lin, Esq.
5288 Spring Mtn. Rd, Ste 103
Las Vegas, Nevada 89146

Laughlin Pharmacy
3080 S Needles Hwy., Suite 1800
Laughlin, NV 89029

Youjin Seo, RPH
[redacted]
Henderson, NV [redacted]

Youjin Seo, RPH c/o
Valley View Medical Center
5330 S Hwy 95
Fort Mohave, AZ 86426

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
OCT 2 1 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

LAUGHLIN PHARMACY & WELLNESS CENTER, Pharmacy License No. PH04520,

YOUJIN SEO, RPH, Certificate of Registration No. 18704, and

THU VO, RPH, Certificate of Registration No. 18661,

Respondents.

Case Nos. 24-289-PH-S
24-289-RPH-A-S
24-289-RPH-B-S

NOTICE OF INTENDED ACTION AND ACCUSATION

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Youjin Seo, RPh (Seo), Certificate of Registration No. 18704, and Respondent Thu Vo, RPh (Vo), Certificate of Registration No. 18661, were pharmacists registered with the Board, and Respondent Laughlin Pharmacy & Wellness Center (Laughlin Pharmacy), Pharmacy License No. PH04520, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Seo and Vo co-owned Laughlin Pharmacy and Vo was managing pharmacist at the time of the events alleged herein.

3. Respondents dispensed and/or directly administered at least 51 syringes of sterile drug products as "weight loss injections" to five (5) different patients between January 3, 2024, and May 24, 2024.

4. The drug products included, without limitation, semaglutide 5mg and tirzepatide 10mg, purchased from and compounded by DeeFlat Pharmacy, Pharmacy License No. PH04171, located in Bullhead City, AZ, using non-sterile methods and adulterated and/or misbranded drugs.

5. The compounded drug products were purchased in vials and dispensed and/or administered in insulin use-only syringes.

6. Respondents maintained no records documenting the purchase of the compounded drug products from DeeFlat Pharmacy.

7. On or about June 5, 2024, Respondent Seo attempted to charge patient M.M-S. an additional cash charge of $90 beyond the required insurance co-pay to fill a prescription for a Dexcom G-7 Sensor.

APPLICABLE LAW

8. Any sterile drug products sold or dispensed by a pharmacy shall be compounded in compliance with NAC 639.6701-.6702, *inclusive*, NAC 639.6705 -.67079, *inclusive*, and related federal law, 21 U.S.C. § 353a and USP-797 standards. NRS 639.100; NRS 639.286.

9. Pursuant to NRS 585.520(1) and (2) it is unlawful to sell or dispense an adulterated or misbranded drug (as defined in NRS 585.380, NRS 585.400, NRS 585.410, NRS 585.420 and/or NRS 585.460). Pursuant to NRS 454.351(1) it is unlawful to sell or dispense any drug which may not be lawfully introduced into interstate commerce under the Federal Food, Drug, and Cosmetic Act.

10. Pursuant to 21 U.S.C. § 331(a), (b) and (c) it is unlawful to engage in the sale and/or distribution of an adulterated or misbranded drug in interstate commerce.

11. No person may administer a dangerous drug without specific statutory authority to do so. NRS 454.213.

12. A pharmacy shall maintain complete, accurate and readily retrievable records of all dangerous drugs purchased and those sold on prescription, dispensed, furnished or disposed of otherwise. NRS 454.286; NRS 454.291; NAC 639.487(2); NAC 639.510(2)(b).

13. Selling or dispensing or permitting to be sold or dispensed substandard drugs or preparations constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(a) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

14. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

15. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

16. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

17. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

18. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy, including recordkeeping. NRS 639.210(15), NRS 639.220(1) and/or NAC 639.510(2)(b).

19. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the

pharmacy by the Board. NRS 639.230(5). Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT ONE

Violations of Federal Law – Dispensing Adulterated or Misbranded Drugs

20. By dispensing adulterated and/or misbranded sterile drug products that were not compounded in compliance with 21 U.S.C. § 353a and USP-797 guidelines, as alleged in paragraphs 3-5 herein, respondents violated 21 U.S.C. § 331(a), (b) and/or (c), and are therefore subject to discipline pursuant to NRS 639.210(11) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT TWO

Violations of State Law – Dispensing Adulterated or Misbranded Drugs

21. By dispensing adulterated and/or misbranded sterile drug products that were not compounded in compliance with NAC 639.6701-.6702, *inclusive*, NAC 639.6705 -.67079, *inclusive*, as alleged in paragraphs 3-5 herein, respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.351(1), NRS 585.520(1) and (2) and/or NRS 639.100(1), and are therefore subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT THREE

Violations of State Law – Unlawful Administration of Drug

22. By directly administering compounded drug products to patients as alleged in paragraphs herein, respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213, and are therefore subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

\\\

\\\

\\\

\\\

COUNT FOUR

Violations of State Law - Recordkeeping

23. By failing to keep and maintain complete, accurate and readily retrievable records accounting for all dangerous drugs as alleged in paragraph 6 herein, respondents violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.286, NRS 454.291, NAC 639.487(2) and/or NAC 639.510(2)(b), and are therefore subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT FIVE

Unprofessional Conduct – Selling or Dispensing Substandard Drugs

24. By dispensing and/or directly administering adulterated and/or misbranded sterile drug products to patients, as alleged herein, respondents sold or dispensed substandard drugs or preparations and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(a), and are subject to discipline pursuant to NRS 639.210(4).

COUNT SIX

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

25. By attempting to charge patient M.M-S. an additional cash charge of $90 beyond the required insurance co-pay to fill a prescription for a Dexcom G-7 Sensor, Respondent Seo was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and all respondents are therefore subject to discipline pursuant to NRS 639.210(4), NRS 639.230(5) and/or NAC 639.945(3).

COUNT SEVEN

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

26. By their conduct as alleged herein, respondents have performed their duties as licensees/registrants in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 639.210(4).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the license and registrations of these respondents.

Signed this 21 day of October 2024.

J. David Wuest, RPh, Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LAUGHLIN PHARMACY & WELLNESS CENTER** **License No. PH04520,** **Respondent.**	**Case No. 24-289-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 21st day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **LAUGHLIN PHARMACY & WELLNESS CENTER, License No. PH04520,** **Respondent.**	**Case No. 24-289-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

AUTHORIZED REPRESENTATIVE FOR
Laughlin Pharmacy & Wellness Center

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 21st day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Laughlin Pharmacy & Wellness Center
3080 S Needles Hwy., Suite 1800
Laughlin, NV 89029

Youjin Seo, Rph
[redacted]
Henderson, NV [redacted]

Youjin Seo, Rph
Valley View Medical Center
5330 S Hwy 95
Fort Mohave, AZ 86426

Thu Vo, Rph
[redacted]
Fort Mohave, AZ [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT
BOARD COORDINATOR I

8

8A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	■ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient.** The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		■ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Alliance Medical Equipment LLC

MDEG Physical Address: 2475 W Cheynne Ave Ste 210

City: North Las Vegas State: NV Zip: 89032

Mailing Address (if different from physical address): [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: 702-596-0018 Website: na

Email: Teddy@alliancemedequipment.com

Name of MDEG Administrator (NAC 639.694): Teddy White

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	■ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Teddy White
	Telephone: 702-596-0018

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9a-3p	■ Tue: 9a-3p	■ Wed: 9a-3p	■ Thurs: 9a-3p	■ Fri: 9a-3p
☐ Sat: Closed	☐ Sun: Closed	☐ Holidays: TBD		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
NA- New application

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: NA _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: Alliance Medical Equipment LLC

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: 702-596-0018 Email: Teddy@alliancemedequipment.com

Contact Person Name: Teddy White

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Teddy White

Print Name of Authorized Person Submitting Application

Teddy W.

Original signature of Authorized Person (copies or stamps not accepted)

8/31/26

Date

Board Use Only	Date Received: 9/11/26	Amount: $500 cc

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 02/27/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATIONIS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER ACRISURE SW PARTNERS INS SVCS LLC 53602363 9960 W CHEYENNE AVE SUITE 240 LAS VEGAS NV 89129	**CONTACT NAME:** **PHONE (A/C, No, Ext):** (866) 467-8730 **FAX (A/C, No):** (888) 443-6112 **E-MAIL ADDRESS:**
INSURED Alliance Medical Equipment LLC 2475 W CHEYENNE AVE NORTH LAS VEGAS NV 89032-4327	**INSURER(S) AFFORDING COVERAGE** — **NAIC#** **INSURER A:** Property and Casualty Insurance Company of Hartford — 34690 **INSURER B:** **INSURER C:** **INSURER D:** **INSURER E:** **INSURER F:**

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED.NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSR	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR [X] General Liability GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			53 SBA CA4M12	03/01/2026	03/01/2027	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $1,000,000 $10,000 $1,000,000 $2,000,000 Excluded
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] ALL OWNED AUTOS [ ] SCHEDULED AUTOS [ ] HIRED AUTOS [ ] NON-OWNED AUTOS						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	
	[ ] UMBRELLA LIAB [ ] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $						EACH OCCURRENCE AGGREGATE	
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [ ] (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A					[ ] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE -EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	
A	Employment Practices Liability Insurance			53 SBA CA4M12	03/01/2026	03/01/2027	Each Claim Limit Annual Aggregate Limit	$25,000 $25,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

The Business Liability Coverage Part includes a Blanket Additional Insured By Contract Endorsement, Form SL 30 32.

CERTIFICATE HOLDER

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Susan L. Castaneda

© 1988-2015 ACORD CORPORATION. All rights reserved.

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Alliance Medical Equipment LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 01/19/2026, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 02/26/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202602266515536
You may verify this certificate online at https://www.nvsilverflume.gov/home

ALLIANCE MEDICAL EQUIPMENT LLC

Member Ownership List

The following identifies the ownership interests of Alliance Medical Equipment LLC for purposes of the Nevada State Board of Pharmacy Medical Products Provider (MDEG) application.

Member / Owner	**Ownership Interest**
Teddy White	70%
Gavin Arnold	30%
Total	**100%**

I certify that the ownership information listed above is accurate and complete as of the date signed below.

Authorized Person: Teddy White

Title: Member / MDEG Administrator

Signature: Teddy W.

Date: 8/31/26

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Alliance Medical Equipment LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 2475 W Cheynne Ave STE 210

City: North Las Vegas State: NV Zip: 89032

Mailing Address (if different from physical address): [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: 702-596-0018 Website:

Licensing Company Email: teddy@alliancemedequipment.com

Section 2: Personal Information

First: Teddy Middle: Josephine Last: White

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Centennial High School			08/15-05/16	
Address		City	State	Zip
10200 W Centennial Pkwy		Las Vegas	NV	89149
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Faith Lutheran Middle School & High School			08/09-06/15	
Address		City	State	Zip
2015 S Hualapai Wy, Las Vegas, NV 89117		Las Vegas	NV	89117
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/19 - Present	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)		City	State	
06/17 - 12/19		Las Vegas	NV	
From - To (MM/YY – MM/YY)		City	State	
06/16 - 06/17		Las Vegas	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Alliance Medical Equipment LLC			01/26-Current	
Business Address		**City**	**State**	**Zip**
2475 W Cheyenne Ave Suite 210		North Las Vegas	NV	89032
Phone	**Title**			
702-596-0018	Owner			
Description of Duties				
Administrative operations, business development and oversight				

Business Name			From - To (MM/YY – MM/YY)	
Telehealth Clinical Evals LLC			05/22-06/26	
Business Address		**City**	**State**	**Zip**
101 Convention Drive Suite 900		Las Vegas	NV	89109
Phone	**Title**			
725-307-3997	Coding Specialist			
Description of Duties				
Ensuring staff and providers are educated on Local Coverage Determinations, policy articles, appropriate HCPC coding, and CPT coding for comprehensize mobility evaluations.				

Business Name			From - To (MM/YY – MM/YY)	
Rider Mobility Inc			10/20-05/22	
Business Address		**City**	**State**	**Zip**
3985 W Cheyenne		North Las Vegas	NV	89032
Phone	**Title**			
702-272-0230	Customer Service Representative			
Description of Duties				
Managing patient intake, verifiying required documentation, scheduling appointments, and coordinating patient communication throughout the process. I also assisted with prior Authorization requests.				

Business Name			From - To (MM/YY – MM/YY)	
Academy Medical Equipment			11/15-09/16	
Business Address		**City**	**State**	**Zip**
No longer in business		NA	NV	NA
Phone	**Title**			
NA	File Clerk			
Description of Duties				
Filing, records management, and general administative support.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Teddy W.
Original Signature (electronic, copies or stamps not accepted)

8/31/26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Teddy White

Print Name (First, Last)

Teddy W.

Original Signature (electronic, copies or stamps not accepted)

8/31/26

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Teddy White, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Teddy W.

Original Signature

8/31/26

Date

Subscribed and Sworn to before me this 31 day of August, 2026

Notary Public Signature

Christian Tapia
Notary Public - State of Nevada
County of Clark
APPT. NO. 10-2427-1
My Appt. Expires: January 16, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Alliance Medical Equipment LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 2475 W Cheyenne Ave. Suite 210

City: Las Vegas State: NV Zip: 89032

Mailing Address (if different from physical address): [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: 702-596-0018 Website:

Licensing Company Email: teddy@alliancemedequipment.com

Section 2: Personal Information

First: Gavin Middle: Last: Arnold

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
San Marcos High School		2017-2021	
Address	**City**	**State**	**Zip**
1615 W San Marcos Blvd	San Marcos	CA	92078
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2026-Current	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)		City	State	
2024-2026		Temecula	CA	
From - To (MM/YY – MM/YY)		City	State	
2003-2024		San Marcos	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Alliance Medical Equipment LLC			08/26-Current
Business Address	**City**	**State**	**Zip**
2475 W Cheyenne Ave Suite 210	North Las Vegas	NV	89032
Phone	**Title**		
702-596-0018	Owner		
Description of Duties			
Assistive technology profressional, Marketing and business development			

Business Name			From - To (MM/YY – MM/YY)
Independent Medical Equipment			06/2025-Current
Business Address	**City**	**State**	**Zip**
3480 US-27	Fruit land Park	FL	34731
Phone	**Title**		
(352) 742-7878	Manager		
Description of Duties			
Assistive technology profressional, sales manager			

Business Name			From - To (MM/YY – MM/YY)
Desert Mobility Equipment			10/2024-Current
Business Address	**City**	**State**	**Zip**
1531 Ford Dr	El Centro	CA	92243
Phone	**Title**		
(442) 271-4051	ATP		
Description of Duties			
Assistive technology profressional			

Business Name			From - To (MM/YY – MM/YY)
Endeavor Medical Supply			01/2025-04/2025
Business Address	**City**	**State**	**Zip**
5552 W Cerritos Ave C	Cypress	CA	90630
Phone	**Title**		
7145221500	ATP		
Description of Duties			
Asstive technology profressional			

Business Name			From - To (MM/YY – MM/YY)
Access Medical Wheelchairs			06/2021-9/2023
Business Address	**City**	**State**	**Zip**
3266 Grey Hawk Ct	Carlsbad	CA	92010
Phone	**Title**		
8009214508	Purchasing agent/ customer service reprentative		
Description of Duties			
Purchase orders, scheduling, intake, record requests			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8/31/26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gavin Arnold

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/31/26

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Gavin Arnold, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/31/26

Date

Subscribed and Sworn to before me this 31 day of August, 2026

Notary Public Signature

Christian Tapia
Notary Public - State of Nevada
County of Clark
APPT. NO. 10-2427-1
My Appt. Expires: January 16, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Alliance Medical Equipment LLC — MDEG License # (if applicable): _____

Physical Address: 2475 W Cheynne Ave Suite 210

City: North Las Vegas — State: NV — Zip: 89032

Mailing Address (if different from physical address): [redacted]

City: Las Vegas — State: NV — Zip: [redacted]

Telephone: 702-596-0018 — Website: _____

Licensing Company Email: AllianceMedicalLV@gmail.com

Section 2: Personal Information

First: Teddy — Middle: Josephine — Last: White

Alias(es, nicknames, name changes, etc.): NA

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Las Vegas — State: nv — Zip: [redacted]

Telephone: [redacted] — Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Centennial High School		08/2015-05/2016	
Address	City	State	Zip
10200 W Centennial Pkwy	Las Vegas	NV	89149
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Faith Lutheran Middle School & High School		08/09-06/2015	
Address	City	State	Zip
2015 S Hualapai Wy, Las Vegas, NV 89117	Las Vegas	NV	89117
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/19-	[redacted]	Las Vegas	NV	[redacted]
06/17-12/19		Las Vegas	NV	
06/16-06/17		Las Vegas	NV	
01/14-06/16		Las Vegas	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Telehealth Clincial Evals			05/22-06/26	
Business Address		**City**	**State**	**Zip**
101 Convention Drive Suite 900		Las Vegas	NV	89109
Phone	**Title**		**Number of Employed Hours**	
725-307-3997	Coding Specialist		8,000	
Description of Duties				
Responsible for educating providers and staff on Local Coverage Determinations, Policy Articles and HCPCS codes Ensure proper application and enforcement of applicable Medicare coverage, coding and documentation polices.				

Business Name			From - To (MM/YY – MM/YY)	
Rider Mobility INC			10/20-5/22	
Business Address		**City**	**State**	**Zip**
3985 W Cheyenne Ave STE 306		North Las Vegas	NV	89032
Phone	**Title**		**Number of Employed Hours**	
702-272-0230	Customer Service Represenative		3,291	
Description of Duties				
Managing patient intake, verifying required documentation, scheduling appointments, and coordinating patient communication throughout the process. Assist with prior authorization submissions.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Teddy W.
Original Signature (electronic, copies or stamps not accepted)

8/31/26
Date

I, Teddy White, **certify that as the MDEG Administrator for**

_____,

that I (initial that you have read and meet the following requirements):

1. TW Have a high school diploma or its equivalent;
2. TW Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. TW Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. TW Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Teddy White
Print Name (First, Last)

Teddy W.
Original Signature (electronic, copies or stamps not accepted)

8/31/26
Date

Board Use Only	Date Received: 9/11/26

8B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☑ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	☑ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		MDEG Business Type (check applicable box)
☑ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☑ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Hudson Medical Co LLC

MDEG Physical Address: 220 E Horizon Dr Ste G

City: Henderson State: NV Zip: 89015

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 7027691399 Website: www.hudsonmedco.com

Email: admin@hudsonmedco.com

Name of MDEG Administrator (NAC 639.694): Ohndeis Mitchell

Entities the MDEG will Serve	Type of MDEG products that will be sold (check all applicable)
☑ Patients by prescriptions	☐ Medical Gases**
☑ Pharmacies[a]	☑ Respiratory Equipment**
☑ Practitioners[a]	☐ Life-sustaining equipment**
☑ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☑ Clinics[a]	☑ Assistive Equipment
☐ Wholesalers[a]	☑ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Ohndeis Mitchell
	Telephone: 904-912-4775

Check the Days the Business will be Opened and provide the Hours of Operation				
☐ Mon:	☐ Tue:	■ Wed: 10-1	■ Thurs: 10-1	☐ Fri:
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): _____

Corporation/Organization Name: Hudson Medical Co LLC

Mailing Address: 220 E Horizon Dr Ste G

City: Henderson State: NV Zip: 89015

Telephone: 7023501966 Email: admin@hudsonmedco.com

Contact Person Name: Melissa Hudson

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: Melissa Hudson

Business Name: Hudson Medical Co LLC

Business Address: 220 E Horizon Dr Ste G

City: Henderson State: NV Zip: 89015

Telephone: 7023501966 Email: admin@hudsonmedicalco.com

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Melissa Hudson

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

09/23/2026

Date

Board Use Only	Date Received: _____ Amount: _____

NEXT INSURANCE US COMPANY

(a stock insurance company)

251 Little Falls Drive
Wilmington, DE 19808
(855) 222-5919

Administered by:

Next First Insurance Agency, Inc.
PO Box 60787
Palo Alto, CA 94306
(855) 222-5919

COMMERCIAL GENERAL LIABILITY DECLARATIONS

CERTAIN COVERAGES IN THE POLICY MAY BE WRITTEN ON A CLAIMS-MADE BASIS. PLEASE READ YOUR POLICY CAREFULLY.

POLICY NUMBER: NXTLFDPXH4-00-GL

Named Insured and Mailing Address: Melissa Hudson
Hudson Medical Co LLC
220 E Horizon Dr Ste G
Henderson, NV 89015

Policy Period: From: 07/09/2026 To: 07/09/2027
at 12:01 a.m. standard time at the mailing address shown above

DESCRIPTION OF BUSINESS	
Insured is:	
_____ Individual / Sole Proprietor	_____Partnership/Joint Venture
x_____ Limited Liability Company	_____Trust
_____ Other - Corporation	
Business of Insured:	Medical Supplies Store

LIMITS OF INSURANCE		
Each Occurrence Limit	$ 1,000,000.00	
Damages to Premises Rented to You Limit	$ 100,000.00	Any one premises
Medical Expense Limit	$ 15,000.00	Any one person
Personal & Advertising Injury Limit	$ 1,000,000.00	Any one person or organization
General Aggregate Limit	$ 2,000,000.00	
Products/Completed Operations Aggregate Limit	$ 2,000,000.00	

Includes copyrighted material of Insurance Services Office, Inc., with its permission.

CLASSIFICATION AND PREMIUM

LOCATION NUMBER	CLASSIFICATION	CODE NO.	PREMIUM BASE	RATE		ADVANCE PREMIUM	
				Prem/ Ops	Prod/Comp Ops	Prem/ Ops	Prod/Comp Ops
	18437		GROSS_SALES	$257.77	$62.23		

State Tax Or Other (if applicable) $ 0.00

TOTAL PREMIUM (SUBJECT TO AUDIT) $ 320.0

PREMIUM SHOWN IS PAYABLE:

At Inception $_____

At Each Anniversary $_____

(If policy period is more than one year and premium is paid in annual installments)

AUDIT PERIOD (IF APPLICABLE)

X_____Annually_____Semi-Annually_____Quarterly_____Monthly

Includes copyrighted material of Insurance Services Office, Inc., with its permission.

Declarations:
COMMON POLICY DECLARATIONS

Insurer: Next Insurance US Company 251 Little Falls Drive Wilmington, DE 19808 1-855-222-5919	**Agency / Broker:** Next First Insurance Agency, Inc. (NFIA) PO Box 60787 Palo Alto, CA 94306 Service Phone: (855) 222-5919 Fax: (650) 644-0101
Administered By: Next First Insurance Agency, Inc. (NFIA) PO Box 60787 Palo Alto, CA 94306 Service Phone: (855) 222-5919 Fax: (650) 644-0101	**Producer Code:** 18721225
Policy Number: NXTLFDPXH4-00-GL	**Previous Policy Number:** N/A
Policy Period: *From:* 07/09/2026 *To:* 07/09/2027 12:01 AM *standard time at the Named Insured's mailing address shown below or the time at which the policy of insurance is applied for, whichever is later.*	
Type of Business: Medical Supplies Store	
Named Insured and Mailing Address: Melissa Hudson Hudson Medical Co LLC 220 E Horizon Dr Ste G Henderson, NV 89015	**Organization Type:** Limited Liability Company **Audit Period:** Auditable - Annual

IN RETURN FOR THE PAYMENT OF PREMIUM, AND SUBJECT TO ALL THE TERMS OF THIS POLICY, WE AGREE WITH YOU TO PROVIDE THE INSURANCE AS STATED IN THIS POLICY.

THIS POLICY CONSISTS OF THE FOLLOWING COVERAGE PARTS FOR WHICH A PREMIUM IS INDICATED. THIS PREMIUM MAY BE SUBJECT TO ADJUSTMENT.	
Coverage Parts:	**Premium:**
Commercial General Liability Coverage Part Privacy and Network Liability Coverage Part	$320.00 $45.00
Applicable State Taxes & Fees	**Surcharge Amount**
Amount Payable at Inception: $60.84	**Total:** $365.00

These Common Policy Declarations and the Coverage Part Declaration(s), together with the Common Policy Forms, the Coverage Part form(s), Policy Conditions and endorsement(s), complete the above numbered policy.

Includes copyrighted material of Insurance Services Office, Inc., with its permission

Declarations:
COMMON POLICY DECLARATIONS

Schedule of Common Locations

In this policy, certain insurance coverages may be specifically designated to your business locations or premises. We've listed the locations below.

Premise Number	Premises Address

Includes copyrighted material of Insurance Services Office, Inc., with its permission

Declarations:
COMMON POLICY DECLARATIONS

Schedule of Common Policy Forms

Your policy includes the Common Policy Forms listed below at time of issue. These forms apply to multiple or all Coverage Parts within your General Liability Policy.

Common Policy Form Schedule	
Form Number and Edition Date	Form Name
NXT-0001 IL 0818	Signature Page
NXT-IL-8007.2-0825	Summary - Transaction Fees
IL 00 17 11 98	Common Policy Conditions
IL 00 21 09 08	Nuclear Energy Liability Exclusion Endorsement (Broad Form)
IL 01 15 01 10	Nevada Changes - Domestic Partnership
IL 02 51 09 07	Nevada Changes - Cancellation and Nonrenewal
NXT-0005 IL 0225	Insured Requested Cancellation
NXT-0006 IL 0920	Calculation of Premium

Includes copyrighted material of Insurance Services Office, Inc., with its permission

Declarations:
COMMON POLICY DECLARATIONS

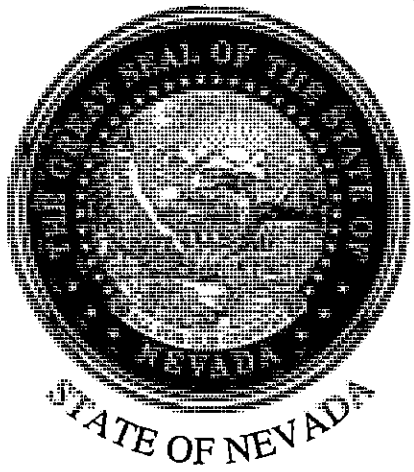
Summary: Other Charges

The price of your policy may include additional taxes, fees, surcharges, or other costs as required by federal or state laws and regulations. We've listed those charges in the table below:

Other Charges Schedule	
Description	Cost/Charge
Other Premiums and Fees	
Service Fee	$47.88
Surcharges and Taxes	

Includes copyrighted material of Insurance Services Office, Inc., with its permission

SECRETARY OF STATE



CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational or qualification, as applicable, documents on file in this office for

Hudson Medical Co LLC

Organizational Documents on File	Filing Date
Articles of Organization	07/08/2026

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence Hudson Medical Co LLC, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, and by virtue of the laws of the State of Nevada since 07/08/2026, and is in good standing in this state.

SECRETARY OF STATE

STATE OF NEVADA

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 07/09/2026.

F V Aguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202607096816277
You may verify this certificate online at
https://www.nvsilverflume.gov/home

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Filed in the Office of	Business Number
F V Aguilar	E58846702026-1
Secretary of State	Filing Number
State Of Nevada	20265884669
	Filed On
	07/08/2026 11:11:55 AM
	Number of Pages
	2

Formation - Limited-Liability Company

- ☑ NRS 86 - Articles of Organization Limited-Liability Company
- ☐ NRS 86.544 - Registration of Foreign Limited-Liability Company
- ☐ NRS 89 - Articles of Organizetion Professional Limited-Liability Company
- ☐ NRS 86.555 - Registration of Professional Foreign Limited-Liability Company

1. Name Being Registered in Nevada: (See Instructions)
Hudson Medical Co LLC

2. Foreign Entity Name: (Name in home jurisdiction)

3. Jurisdiction of Formation: (Foreign Limited-Liability Companies)
3a) Jurisdiction of formation: 3b) Date formed:
3c) I declare this entity is in good standing in the jurisdiction of its formation. ☐

4. Registered Agent for Service of Process*: (check only one box)
☐ Commercial Registered Agent (name only below) ☑ Noncommercial Registered Agent (name and address below) ☐ Office or position with Entity (title and address below)

Melissa Hudson
Name of Registered Agent OR Title of Office or Position with Entity

220 E Horizon Dr Ste H | Henderson | Nevada | 89015
Street Address | City | Zip Code

Mailing Address (If different from street address) | City | Nevada | Zip Code

4a. Certificate of Acceptance of Appointment of Registered Agent:
I hereby accept appointment as Registered Agent for the above named Entity. If the registered agent is unable to sign the Articles of Incorporation, submit a separate signed Registered Agent Acceptance form.

X Melissa Hudson — 07/08/2026
Authorized Signature of Registered Agent or On Behalf of Registered Agent Entity — Date

5. Management: (Domestic Limited-Liability Companies only)
Company shall be managed by: (check one box) ☑ Manager(s) **OR** ☐ Member(s)

6. Name and Address of each Manager(s) or Managing Member(s): (NRS 86 and NRS 86.544, see instructions)
Name and Address of the Original Manager(s) and Member(s): (NRS 89, see instructions)
IMPORTANT:
A certificate from the regulatory board must be submitted showing that each individual is licensed at the time of filing.

1) Melissa Hudson
Name

220 E Horizon Dr Ste G | Henderson | NV | 89015
Address | City | State | Zip Code

7. Dissolution Date: (Domestic only)
Latest date upon which the company is to dissolve (if existence is not perpetual):

This form must be accompanied by appropriate fees.

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Formation - Limited-Liability Company

Continued, Page 2

8. Purpose/ Profession to be Practiced: (NRS 89 only)

9. Series and/or Restricted Limited-Liability Company: (Optional)

Check box if a Series Limited-Liability Company ☐

Domestic Limited-Liability Company"s only: The Limited-Liability Company is a Restricted Limited-Liability Company ☐

10. Records Office: (Foreign Limited-Liability Companies)

Address | City | State | Zip code

Country

11. Street Address of Principal Office: (Foreign Limited-Liability Companies)

Address | City | State | Zip code

Country

12. Name, Address and Signature of the Organizer: (NRS 86, NRS 89 -Each Organizer must be a licensed professional.)

*Foreign Limited-Liability Company - In the event the designated Agent for Service of Process resigns and is not replaced or the agent's authority has been revoked or the agent cannot be found or served with exercise of reasonable diligence, then the Secretary of State is hereby appointed as the Agent for Service of Process.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the Office of the Secretary of State.

Name and Signature of Manager or Member: (NRS 86.544 only)

See Instructions

MELISSA HUDSON			United States
Name			Country
220 E Horizon Dr Ste G	Henderson	NV	89015
Address	City	State	Zip/Postal Code

X MELISSA HUDSON (attach additional page if necessary)

AN INITIAL LIST OF OFFICERS MUST ACCOMPANY THIS FILING

Please include any required or optional information in space below:
(attach additional page(s) if necessary)

This form must be accompanied by appropriate fees.

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Initial List and State Business License Application

Initial List Of Officers, Managers, Members, General Partners, Managing Partners, or Trustees:

Hudson Medical Co LLC

NAME OF ENTITY

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: *Read instructions before completing and returning this form.*

Please indicate the entity type (check only one):

☐ Corporation

☐ This corporation is publicly traded, the Central Index Key number is:

☐ Nonprofit Corporation (see nonprofit sections below)

☑ Limited-Liability Company

☐ Limited Partnership

☐ Limited-Liability Partnership

☐ Limited-Liability Limited Partnership (if formed at the same time as the Limited Partnership)

☐ Business Trust

Filed in the Office of	Business Number
FVAguilar	E58846702026-1
Secretary of State	Filing Number
State Of Nevada	20265884671
	Filed On
	07/08/2026 11:11:55 AM
	Number of Pages
	2

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee.

☐ 001 - Governmental Entity

☐ 006 - NRS 680B.020 Insurance Co, provide license or certificate of authority number

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is $200.00. Those claiming and exemption under 501(c) designation must indicate by checking box below.

☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee.
Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C $ 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit $200.00 for the state business license.

☐ Unit-owners' Association ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. $501(c)

For nonprofit entities formed under NRS Chapter 82 and 80: **Charitable Solicitation Information - check applicable box**

Does the Organization intend to solicit charitable or tax deductible contributions?

☐ No - no additional form is required

☐ Yes - the "Charitable Solicitation Registration Statement" is required.

☐ The Organization claims exemption pursuant to NRS 82A 210 - the "Exemption From Charitable Solicitation Registration Statement" is required

"Failure to include the required statement form will result in rejection of the filing and could result in late fees."

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Initial List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners or Trustees:

CORPORATION, INDICATE THE Manager:

Name	Country
Melissa Hudson	USA

Address	City	State	Zip/Postal Code
220 E Horizon Dr Ste G	Henderson	NV	89015

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the office of the Secretary of State.

X MELISSA HUDSON

Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

Title	Date
Manager	07/08/2026

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Hudson Medical Co LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 220 E Horizon Dr Ste G

City: Henderson State: NV Zip: 89015

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 7027691399 Website:

Licensing Company Email: admin@hudsonmedco.com

Section 2: Personal Information

First: Melissa Middle: Last: Hudson

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address: 220 E Horizon Dr Ste H

City: Henderson State: Zip: 89015

Telephone: 7027691399 Email: melissa@hudsonmedco.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of Phoenix			2026 2029	
Address		City	State	Zip
Online		Henderson	NV	89014
Diploma/Degree obtained, if any				
Master of Management				

School Name			From - To (MM/YY – MM/YY)	
CSN			2021 2026	
Address		City	State	Zip
College Dr		Henderson	NV	89002
Diploma/Degree obtained, if any				
Associate of Arts				

School Name			From - To (MM/YY – MM/YY)	
Basic High School			1996 2000	
Address		City	State	Zip
Palo Verde		Henderson	NV	89015
Diploma/Degree obtained, if any				
High School Diploma				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2019 current	[redacted]	Henderson	NV	[redacted]
2013 2019		Henderson	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Conner Family & Associates LLC			04/2007 Present
Business Address	**City**	**State**	**Zip**
220 E Horizon Dr Ste H	Henderson	NV	89015
Phone	**Title**		
7023684112	Owner		
Description of Duties			
Allstate Insurance Agency Owner			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered à license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

07/09/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Melissa Hudson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

07/09/2026

Date

Please have this section completed in the presence of a Notary Public.

State of NV, ss. County of Clark

I, Melissa Hudson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/9/2026

Date

Subscribed and Sworn to before me this 9 day of July 2026

Notary Public Signature

ANUKUL YEZZA
Notary Public - State of Nevada
County of Clark
Appt. No. 23-4198-01
My Appt. Expires: January 20, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Hudson Medical Co LLC — MDEG License # (if applicable): _____

Physical Address: 220 E Horizon Dr Ste G

City: Henderson — State: NV — Zip: 89015

Mailing Address (if different from physical address): _____

City: _____ — State: _____ — Zip: _____

Telephone: 7023501966 — Website: www.hudsonmedco.com

Licensing Company Email: admin@hudsonmedco.com

Section 2: Personal Information

First: Ohndeis — Middle: S — Last: Mitchell

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Las Vegas — State: Nv — Zip: [redacted]

Telephone: [redacted] — Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Penn Foster High School		01/2002-05/2006	
Address	**City**	**State**	**Zip**
925 Oak Street	Scranton	Pa	18515
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Concorde Career College		09/2010-09/2012	
Address	**City**	**State**	**Zip**
7259 Salisbury Rd Suite 120	Jacksonville	Fl	32256
Diploma/Degree obtained, if any			
Associate - Patient Care Tech			

School Name		From - To (MM/YY – MM/YY)	
Nevada Career Institute		11/2026-	
Address	**City**	**State**	**Zip**
3231 N Decatur Blvd #201	Las Vegas	Nv	89130
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2026-Present	[redacted]	Las Vegas	Nv	[redacted]
06/2022-08/2026		Jacksonville	Fl	
08/2011-06/2022		Jacksonville	Fl	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Comfort Keepers Inc. Summerlin				From - To (MM/YY – MM/YY): 05/2026 - Present
Business Address	City: Las Vegas		State: Nv	Zip
Phone: 702-385-1000	Title: CNA/Caregiver			Number of Employed Hours: 30 hr a wk
Description of Duties				

Business Name: Spring Mountain Treatment Center				From - To (MM/YY – MM/YY): 06/2026 - 09/2026
Business Address: 7000 Spring Mountain Treatment Center	City: Las Vegas		State: Nv	Zip
Phone: 702-873-2400	Title: Mental Health Tech			Number of Employed Hours: 40 hr a wk
Description of Duties				

Business Name: UF Health Jacksonville				From - To (MM/YY – MM/YY): 09/2024-10/2025
Business Address: 655 8th Street W	City: Jacksonville		State: Fl	Zip: 32209
Phone: 904-244-0411	Title: Medical Staff Coordinator			Number of Employed Hours: 40 hrs wk
Description of Duties: As a Medical Staff Coordinator at UF Health Jacksonville, I managed comprehensive onboarding and credentialing workflows to ensure all medical staff met hospital, regulatory, and accreditation standards. I maintained accurate provider r				

Business Name: Fresenius Medical Center				From - To (MM/YY – MM/YY): 04/2019-11/2022
Business Address: Multiple	City: Jacksonville		State: Fl	Zip
Phone	Title: PCT/ Dialysis Tech /			Number of Employed Hours: 40 hr wk
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address	City		State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Ohndeis Mitchell, certify that as the MDEG Administrator for

Hudson Medical Co LLC,

that I (initial that you have read and meet the following requirements):

1. OM Have a high school diploma or its equivalent;
2. OM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. OM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. OM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ohndeis Mitchell
Print Name (First, Last)



Original Signature (electronic, copies or stamps not accepted)

September 23, 2026
Date

Board Use Only	Date Received:

OHNDEIS MITCHELL

Las Vegas, NV | [redacted] | [redacted]

PROFESSIONAL EXPERIENCE

Mental Health Technician

Spring Mountain Treatment Center - Las Vegas, NV | *June 2026 - Present*

- Provide direct patient supervision and support in a behavioral-health treatment environment.
- Conduct required safety observations at 15-minute intervals or according to individualized patient precautions.
- Monitor patients for behavioral, physical, environmental, and safety concerns.
- Promptly report changes in patient condition or behavior to nursing and clinical personnel.
- Document timely and accurate clinical observations in patient medical records.
- Assist patients with activities of daily living and basic patient-care needs.
- Support implementation of individualized treatment and safety plans.
- Assist patients with mobility, positioning, transfers, and other physical needs when required.
- Assist patients who use wheelchairs, walkers, or other mobility-assistive devices while maintaining appropriate positioning and safety.
- Observe patients using prescribed medical or respiratory equipment and report displacement, malfunction, patient intolerance, or other concerns to licensed clinical personnel.
- Follow established infection-prevention and patient-safety procedures.
- Assist with admissions, transfers, discharges, patient movement, and unit activities as assigned.
- Communicate with nurses, physicians, therapists, patients, families, and other members of the treatment team.
- Maintain confidentiality and comply with HIPAA, facility policies, patient-rights requirements, and established healthcare standards.
- Respond promptly to safety concerns and follow escalation procedures.

Medical Caregiver

Comfort Keepers Home Care - Jacksonville, FL | *January 2023 - Present*

- Provide direct patient care and assistance with activities of daily living in accordance with individualized patient care plans.
- Assist patients with bathing, dressing, grooming, toileting, nutrition, mobility, transfers, positioning, and personal-care needs.
- Monitor and document changes in patient condition and promptly communicate concerns to appropriate healthcare personnel.
- Obtain and document vital signs in accordance with patient care plans and organizational requirements.
- Assist with medication administration or medication reminders as authorized.
- Maintain accurate electronic patient-care records and documentation.
- Assist patients with safe ambulation and transfers to reduce risk of falls and injury.
- Assist patients with proper use, positioning, adjustment, and fitting of durable medical equipment and mobility-assistive devices, including wheelchairs, walkers, canes, transfer devices, bedside commodes, shower chairs, and other prescribed assistive equipment.
- Assist with fitting and adjustment of mobility equipment to improve patient positioning, safety, and comfort.
- Observe durable medical equipment for visible damage, improper fit, instability, or other safety concerns and report issues to appropriate healthcare personnel.
- Educate patients and caregivers regarding safe use, handling, cleaning, and storage of prescribed durable medical equipment.
- Assist patients using prescribed pulmonary and respiratory equipment, including oxygen masks, nasal cannulas, respiratory tubing, nebulizer equipment, and related respiratory supplies.
- Assist with fitting and positioning of respiratory masks, nasal cannulas, and tubing for patient comfort and proper use.
- Assist patients with CPAP or BiPAP masks, headgear, tubing, humidification chambers, and related supplies when included in the patient's care plan.
- Inspect respiratory equipment and tubing for visible damage, contamination, loose connections, or improper positioning.
- Report malfunctioning or improperly fitting respiratory equipment to nurses, supervisors, healthcare providers, or medical-equipment suppliers.
- Assist diabetic patients with prescribed glucose-monitoring routines and use of diabetic testing supplies.
- Handle and organize blood glucose meters, test strips, lancets, lancing devices, alcohol preparation supplies, and sharps-disposal containers.
- Assist with blood glucose monitoring as permitted by the patient's care plan and scope of responsibility.
- Document glucose readings and report abnormal results according to established procedures.
- Reinforce proper storage and handling of diabetic testing supplies.
- Monitor patient medical-supply needs and notify patients, caregivers, clinicians, or suppliers when replacement supplies are needed.
- Clean and disinfect reusable patient-care equipment according to care plans, manufacturer instructions, and organizational requirements.

- Follow infection-control procedures when handling medical equipment, respiratory accessories, diabetic supplies, and other patient-care items.
- Identify and report defective, damaged, contaminated, expired, or unsafe patient equipment and medical supplies.
- Train and mentor newly hired caregivers regarding patient care, safety procedures, documentation, equipment handling, and infection control.
- Communicate with patients, family members, nurses, physicians, therapists, and other healthcare professionals regarding patient needs.
- Maintain patient dignity, confidentiality, safety, and independence while providing direct care.

Medical Claims Analyst

North Florida Surgeons PA - Jacksonville, FL | *September 2025 - April 2026*

- Reviewed patient medical records, provider documentation, procedure notes, orders, and supporting healthcare information for completeness and accuracy.
- Identified incomplete or inconsistent medical documentation and coordinated corrections with providers and clinical personnel.
- Reviewed healthcare services, procedures, medical supplies, and supporting documentation.
- Utilized electronic health record systems to access and review patient clinical information.
- Maintained accurate documentation of patient-care services and medical records.
- Communicated with physicians, clinical employees, and administrative personnel regarding documentation discrepancies.
- Maintained confidentiality of medical information in accordance with HIPAA requirements.
- Assisted in identifying documentation trends and recommended improvements to healthcare recordkeeping processes.

Medical Staff Coordinator

UF Health Jacksonville - Jacksonville, FL | *September 2024 - October 2025*

- Coordinated onboarding and administrative support for physicians and other members of the hospital medical staff.
- Maintained accurate medical staff records and required healthcare documentation.
- Verified completion of required licenses, certifications, professional documentation, and hospital requirements.
- Coordinated communication between physicians, clinical departments, HR, administration, and other hospital personnel.
- Assisted with organization and maintenance of healthcare records and compliance documentation.
- Prepared staffing, productivity, and operational reports for hospital leadership.
- Monitored documentation deadlines and followed up on missing or expiring healthcare records.
- Supported hospital operations through accurate recordkeeping and coordination across clinical departments.
- Maintained confidential healthcare information in accordance with HIPAA and organizational policies.
- Assisted with internal reviews and production of required healthcare documentation.

Patient Care Technician / Lead Medical Assistant

Fresenius Medical Center - Jacksonville, FL | *April 2019 - November 2022*

- Provided direct hands-on patient care under the supervision of licensed healthcare professionals.
- Prepared patients, equipment, treatment areas, and medical supplies for scheduled care.
- Obtained and documented patient vital signs, weight, symptoms, treatment information, and other required clinical measurements.
- Monitored patients during treatment and promptly communicated changes in condition to nursing staff.
- Assisted nursing personnel in implementing individualized patient-care plans.
- Assisted with patient mobility, positioning, transfers, and other physical needs.
- Assisted patients with fitting, positioning, adjustment, and safe use of durable medical equipment and mobility-assistive devices.
- Assisted with wheelchairs, walkers, transfer devices, positioning equipment, and other prescribed assistive equipment.
- Inspected assistive equipment for stability, cleanliness, proper positioning, and visible signs of damage.
- Assisted clinical personnel with setup and patient application of prescribed respiratory and pulmonary equipment.
- Assisted with oxygen masks, nasal cannulas, oxygen tubing, connectors, nebulizer accessories, and related respiratory supplies.
- Assisted with selecting appropriately sized respiratory interfaces when directed by licensed clinical personnel.
- Assisted with fitting masks and cannulas to patients for comfort and proper positioning.
- Checked respiratory tubing and connections for proper placement and reported equipment concerns to nursing personnel.
- Observed patients using respiratory equipment and promptly reported intolerance, displacement, leakage, or other safety concerns.
- Assisted diabetic patients with blood glucose monitoring and diabetic testing supplies.
- Handled glucose meters, test strips, lancets, lancing devices, alcohol preparation supplies, and sharps containers.
- Performed or assisted with point-of-care blood glucose testing within authorized scope and facility policy.
- Documented glucose testing and communicated abnormal results to nursing staff.
- Reinforced clinical instructions regarding safe handling and storage of diabetic monitoring supplies.
- Prepared, organized, inspected, and maintained patient-care supplies and treatment areas.
- Checked medical supplies for expiration dates, package integrity, cleanliness, and appropriate storage.
- Maintained appropriate inventory levels and communicated restocking needs.
- Organized patient-care equipment and supplies to ensure availability for clinical use.

- Cleaned and disinfected reusable patient-care equipment in accordance with infection-control requirements.
- Followed standard precautions and OSHA requirements involving blood, bodily fluids, sharps, contaminated materials, and reusable medical equipment.
- Identified defective, damaged, contaminated, expired, or unsafe equipment and removed it from use or reported it to appropriate personnel.
- Documented clinical services, patient observations, and treatment information in patient medical records.
- Assisted with coordination of patient flow, treatment schedules, clinical assignments, and daily workflow.
- Served in a lead role supporting nursing and clinical staff.
- Trained and supported new clinical employees regarding patient-care procedures, equipment use, medical-supply handling, infection prevention, documentation, and safety.
- Communicated with nurses, physicians, patients, caregivers, and other members of the healthcare team.
- Maintained patient safety, dignity, privacy, and confidentiality throughout treatment.

MEDICAL EQUIPMENT & PATIENT SUPPLY EXPERIENCE

- Durable Medical Equipment (DME)
- Wheelchairs, walkers, canes, transfer equipment, bedside commodes, shower chairs, and patient positioning equipment
- Mobility-assistive device fitting and adjustment
- Patient and caregiver instruction regarding equipment use
- Equipment safety inspection
- Pulmonary and respiratory equipment
- Oxygen masks, nasal cannulas, respiratory and oxygen tubing, connectors, and related accessories
- Nebulizer equipment and accessories
- CPAP/BiPAP masks, headgear, tubing, and related accessories
- Respiratory-mask fitting and positioning
- Diabetic testing and monitoring supplies
- Blood glucose meters, test strips, lancets and lancing devices
- Alcohol preparation supplies and sharps-disposal containers
- Blood glucose monitoring
- Medical-supply inventory and restocking
- Equipment cleaning and disinfection
- Infection-control procedures
- Identification of damaged, contaminated, defective, or expired supplies
- Clinical documentation and electronic medical records
- Patient safety and risk reduction

EDUCATION

Patient Care Technician Certification – Concorde Career Institute
Jacksonville, FL
Graduated September 2012

Concorde Career Institute

7259 Salisbury Road
Jacksonville, FL

Be It Known That

Ohndeis Mitchell

Having successfully completed the required program of instruction and having been found duly qualified in the subjects of the program, is hereby awarded this diploma

Patient Care Technician

Given at Jacksonville, FL this date Thursday, September 13, 2012.

Barbara Egan
Academic Dean

Campus President

8C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located? ■ Nevada ☐ Out-of-State

[a]Is the business also a wholesaler? (NRS 639.016) ☐ Yes ■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		MDEG Business Type (check applicable box)
☐ New MDEG ■ Ownership Change* ☐ Name Change* ☐ Location Change*	* If making a change, provide current license number: M P01308	■ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Strive Medical LLC

MDEG Physical Address: 3111 S Valley View Blvd, Ste. B118

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address): 7000 Cardinal Place - QRA Facility Licensing

City: Dublin State: OH Zip: 43017

Telephone: 888-771-9229 Website: www.strivemedical.com

Email: licensure@cardinalhealth.com

Name of MDEG Administrator (NAC 639.694): Angelina Galindo

Entities the MDEG will Serve	Type of MDEG products that will be sold (check all applicable)
■ Patients by prescriptions ☐ Pharmacies[a] ☐ Practitioners[a] ☐ Hospitals/Clinics[a] ☐ Clinics[a] ☐ Wholesalers[a] ☐ Other business entities (specify)[a]:	☐ Medical Gases** ☐ Respiratory Equipment** ☐ Life-sustaining equipment** ☐ Parenteral and Enteral Equipment** ☐ Assistive Equipment ■ Diabetic Supplies ☐ Orthotics and Prosthetics ■ Others: Home Medical Supplies
This application is ONLY required if MDEG products will be sold to patients by prescription. [a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954): Name: N/A Telephone: N/A

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8 am to 5 pm	■ Tue: 8 am to 5 pm	■ Wed: 8 am to 5 pm	■ Thurs: 8 am to 5 pm	■ Fri: 8 am to 5 pm
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare - 6683060004/Medicaid - 1407256266

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A	Credentials: N/A	%: N/A
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: Texas

Parent Company (if any): Strive Acquisition, LLC (Parent Company of Strive Medical LLC)

Corporation Name: Cardinal Health Inc. (Ultimate Holding Company)

Mailing Address: 7000 Cardinal Place

City: Dublin State: OH Zip: 43017

Telephone: 614-757-5000 Email: licensure@cardinalhealth.com

Contact Person Name: LaToyia Martin

Date of SEC Registration: 08/04/1983	SEC Registration Number: 721371	Stock Exchange Symbol: CAH

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Keegan Chamberlain

Print Name of Authorized Person Submitting Application

K Chamberlain

Original signature of Authorized Person (copies or stamps not accepted)

08/03/2024

Date

Board Use Only	Date Received: 8/5/24	Amount: $800 CK 1696 2395

CardinalHealth

August 3, 2026

Dave Wuest, Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste. 206
Reno, NV 89521

RE: Explanation of Disciplinary History
Strive Medical LLC – Las Vegas, NV

Dear Mr. Wuest:

This letter is provided in conjunction with our affirmative response to question 3 on our application for our Out-of-State Wholesale Distributor License. We have the following discipline to report for great grandparent owner of Strive Medical, LLC ("Strive"), RGH Enterprises, LLC. Importantly, Strive, the entity that is the subject of this application, has no discipline to report.

In March 2015, the RGH pharmacy located in Twinsburg, OH, was issued a citation and fined $500 by the Maine Board of Pharmacy, for failure to timely report a change in the facility's pharmacist-in-charge. This failure to report within the seven-day time frame was due to the unavailability of the corporate official authorized to sign the application. RGH paid the fine to the Maine State Board of Pharmacy; additionally, RGH has undertaken a process to ensure regulatory notifications occur in a timely manner.

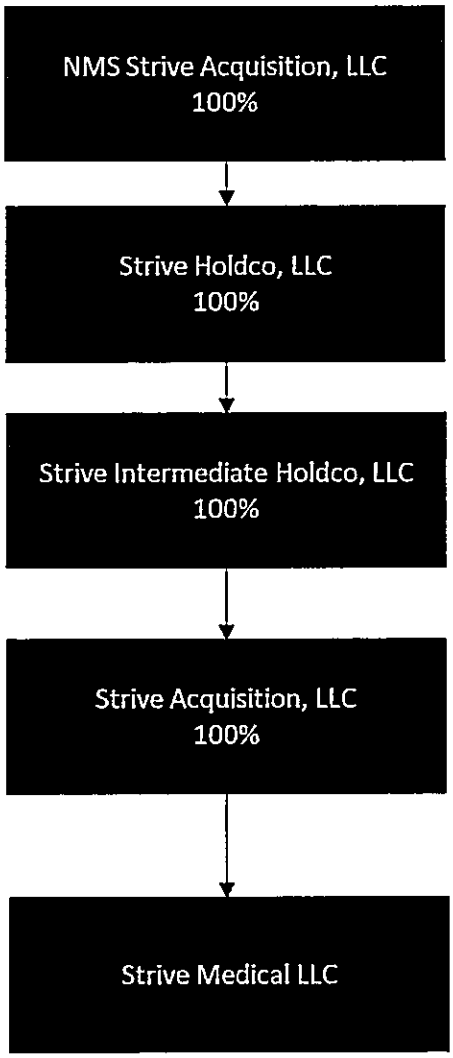
In April 2016, the Hawaii Board of Pharmacy took derivative action against the Twinsburg, OH, facility based on the action described above. RGH entered a Settlement Agreement with Hawaii and agreed to pay a $250 fine; the matter was closed on May 6, 2016.

On December 5, 2024, the Wisconsin Pharmacy Board ("Wisconsin Board") entered into a proposed stipulation and order ("Order") with Edgepark's pharmacy under its Wisconsin Nonresident Pharmacy License, License No. 1251-43. The Order resolved complaints arising from issues with the Edgepark's administrative processes associated with insurance verifications and obtaining prior authorizations from services provided by the pharmacy between March 2021 through January 2024. The deficiencies that led to the complaints have been fully resolved by Edgepark's pharmacy. Edgepark received a reprimand and was required to pay a small administrative fine plus costs.

In July 2026, the Pennsylvania Board of Pharmacy ("Pennsylvania Board") took derivative disciplinary action against the Pharmacy based the 2024 disciplinary action taken by the Wisconsin Board against the Pharmacy. On July 28, 2026, Edgepark entered into a Consent Agreement with the Pennsylvania Board to resolve the derivative action. The Consent Agreement imposed a Public Reprimand against Edgepark's Pennsylvania nonresident pharmacy license, which constitutes reportable discipline under Pennsylvania Board laws and rules.

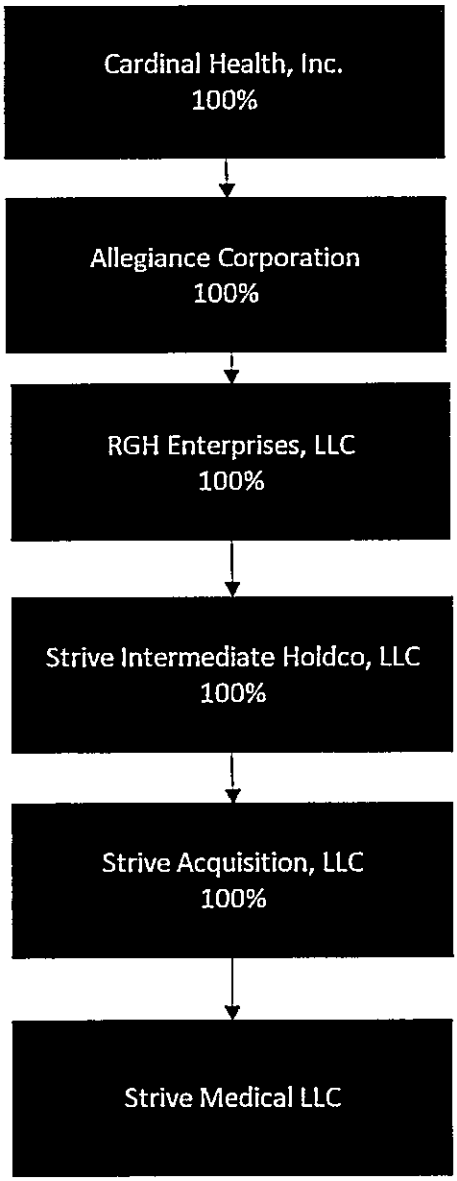
Attachment A

Strive Medical LLC – Legal Entity Structure (Pre-Closing)



Attachment A

Cardinal Health – Legal Entity Structure (Post-Closing)



If you have any questions, Cory Kopitzke, Assistant General Counsel, Regulatory at Cory.Kopitzke01@cardinalhealth.com.

Sincerely,

Keegan Chamberlain
Director, Quality Management

CardinalHealth™

June 30, 2026

To whom it may concern:

This is a declaration and confirmation by Cardinal Health, Inc. and its subsidiaries exclusively that:

Cardinal Health is self-insured for products, completed operations liability and pharmacist professional liability. You will not be named as additional insured for any of the self-insured retention limits of the product liability, completed operations liability, and pharmacist professional liability coverages. Cardinal Health's self-insurance is backed by its financial strength documented in financial statements found at www.cardinalhealth.com. The existence of self-insurance within Cardinal Health's insurance program does not change any contractual obligation we may have, and shall not be deemed to exceed the scope of coverage and/or limits required, under our written contract or agreement with you.

As respects to the Automobile Liability, Automobile Physical Damage, Comprehensive, and Collision coverage is self-insured for all owned and leased vehicles.

Please direct any questions or concerns to GMB-DUB-RiskManagement@cardinalhealth.com.

Denise Johnston
Director, Risk Management

enc.

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 08/07/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. Philadelphia PA Office 100 North 18th Street 16th Floor Philadelphia PA 19103 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Cardinal Health, Inc. (See Additional Page) 7000 Cardinal Place Dublin OH 43017 USA	INSURER A: XL Specialty Insurance Co	37885
	INSURER B: XL Insurance America Inc	24554
	INSURER C: Greenwich Insurance Company	22322
	INSURER D: Indian Harbor Insurance Company	36940
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570122321493 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
C	X COMMERCIAL GENERAL LIABILITY			RGD943716721	06/30/2026	06/30/2027	EACH OCCURRENCE	$5,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
	X Liquor Liability Included						MED EXP (Any one person)	
	GEN'L AGGREGATE LIMIT APPLIES PER:						PERSONAL & ADV INJURY	$5,000,000
	X POLICY PRO-JECT LOC						GENERAL AGGREGATE	$5,000,000
	OTHER:						PRODUCTS - COMP/OP AGG	Excluded
							Liquor Liability Lim	Included
C	AUTOMOBILE LIABILITY			RAD943716821	06/30/2026	06/30/2027	COMBINED SINGLE LIMIT (Ea accident)	$5,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
B	X UMBRELLA LIAB X OCCUR			US00092147LI26A	06/30/2026	06/30/2027	EACH OCCURRENCE	$5,000,000
	EXCESS LIAB CLAIMS-MADE			SIR applies per policy terms & conditions			AGGREGATE	$5,000,000
	DED X RETENTION						Products/Completed O	Excluded
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			RWD943512521 (AOS)	06/30/2026	06/30/2027	X PER STATUTE OTH-ER	
B	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N (Mandatory in NH)	N/A		RWR943512621 (WI)	06/30/2026	06/30/2027	E.L. EACH ACCIDENT	$5,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	$5,000,000
							E.L. DISEASE-POLICY LIMIT	$5,000,000
D	E&O - Professional Liability - Primary			RGD943797707 E&O SIR applies per policy terms & conditions	06/30/2026	06/30/2027	Each Claim	$5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

The Professional Liability policy is claims Made.

CERTIFICATE HOLDER

Cardinal Health, Inc.
7000 Cardinal Place
Dublin OH 43017 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central Inc

Holder Identifier : Z

Certificate No : 570122321493

©1988-2015 ACORD CORPORATION. All rights reserved.

AGENCY CUSTOMER ID: 570000070825
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Cardinal Health, Inc.
POLICY NUMBER: See Certificate Number: 570122321493	
CARRIER: See Certificate Number: 570122321493 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 FORM TITLE: Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	WORKERS COMPENSATION							
A		N/A		RWR300142408 (AK)	06/30/2026	06/30/2027		
	OTHER							
A	Excess Workers Compensation			RWE943514321 Xs Work Comp - OH SIR applies per policy terms & conditions	06/30/2026	06/30/2027	EL Each Accident	$4,500,000
							EL Disease - Ea Empl	$4,500,000

© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: 570000070825
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Cardinal Health, Inc.
POLICY NUMBER	
See Certificate Number: 570122321493	
CARRIER / NAIC CODE	EFFECTIVE DATE:
See Certificate Number: 570122321493	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Evidence of Coverage

As respects the Commercial General Liability Policy:
Additional Insured Managers or Lessors of Premises : as required by written contract
Additional Insured Owners, Lessees or Contractors - Scheduled Persons or Organization : as required by written contract
Coverage provided to the additional insured is required by a contract or agreement, the insurance afforded to such additional insured will not be broader than that which you are required by the contract or agreement to provide for such additional insured and shall not increase the applicable Limits of Insurance

As respects the Automobile Liability Policy:
Coverage symbol 1 (Any Auto) applies to Automobile Liability which includes coverage for Hired / Non-Owned Autos
Lessor - Additional Insured: all leased autos.
The policy will pay as interest may appear, you (Cardinal Health) and the lessor named in this endorsement for "loss" to a "leased auto".
Additional Insured Where Required under Written Contract or Agreement Endorsement

As respects General Liability, Automobile Liability, and Workers Compensation Policies:
Waiver of Subrogation is permitted as required by written contract or agreement executed prior to loss and in accordance with the terms, conditions and exclusions of the applicable policies.

ACORD 101 (2008/01)
© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: 570000070825
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Cardinal Health, Inc.
POLICY NUMBER	
See Certificate Number: 570122321493	
CARRIER / NAIC CODE	EFFECTIVE DATE:
See Certificate Number: 570122321493	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 FORM TITLE: Certificate of Liability Insurance

Named Insured Listing

Named Insured Listing includes but is not limited to the following:
A+ Secure Packaging, LLC
Abilene Nuclear, LLC
Acuity GPO, LLC
ADS Parent, LLC
ADS Interco, LLC
ADS Buyer, LLC
Aero-Med, LLC
Allegiance (BVI) Holding Co. Ltd.
Allegiance Corporation
Allegiance I, LLC
C. International, Inc.
Cardinal Health (Shanghai) Medical Devices Co., Ltd.
Cardinal Health 100, LLC
Cardinal Health 105, LLC
Cardinal Health 107, LLC
Cardinal Health 108, LLC
Cardinal Health 110, LLC
Cardinal Health 112, LLC
Cardinal Health 113, LLC
Cardinal Health 114, Inc.
Cardinal Health 115, LLC
Cardinal Health 116, LLC
Cardinal Health 118, LLC
Cardinal Health 119, LLC
Cardinal Health 121, LLC
Cardinal Health 122, LLC
Cardinal Health 123, LLC
Cardinal Health 124, LLC
Cardinal Health 125, LLC
Cardinal Health 126, LLC
Cardinal Health 127, Inc.
Cardinal Health 128, LLC
Cardinal Health 130, LLC
Cardinal Health 131, LLC
Cardinal Health 132, LLC
Cardinal Health 133, Inc.
Cardinal Health 134, LLC
Cardinal Health 135, LLC
Cardinal Health 2, LLC
Cardinal Health 200, LLC
Cardinal Health 201 Canada L.P.
Cardinal Health 201, LLC
Cardinal Health 215, LLC
Cardinal Health 222 (Thailand) Ltd.
Cardinal Health 23 Funding, LLC
Cardinal Health 23, LLC
Cardinal Health 242, LLC
Cardinal Health 247, Inc.

© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: 570000070825
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Cardinal Health, Inc.
POLICY NUMBER	
See Certificate Number: 570122321493	
CARRIER / NAIC CODE	EFFECTIVE DATE:
See Certificate Number: 570122321493	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Named Insureds Continued

Cardinal Health 249, LLC
Cardinal Health 3, LLC
Cardinal Health 414, LLC
Cardinal Health 418, Inc.
Cardinal Health 5, LLC
Cardinal Health 524, LLC
Cardinal Health 529, LLC
Cardinal Health 7, LLC
Cardinal Health 8, LLC
Cardinal Health Australia 503 Pty Ltd.
Cardinal Health Austria 504 GmbH
Cardinal Health Belgium 505 BV
Cardinal Health Canada Inc.
Cardinal Health Capital Corporation
Cardinal Health Cardiology Solutions, LLC
Cardinal Health Chile Limitada
Cardinal Health Colombia S.A.S.
Cardinal Health Commercial Technologies, LLC
Cardinal Health Corporate Solutions, LLC
Cardinal Health D.R. 203 II Ltd.
Cardinal Health do Brasil Ltda.
Cardinal Health Finance
Cardinal Health Finland Oy
Cardinal Health Foundation
Cardinal Health France 506 SAS
Cardinal Health Funding, LLC
Cardinal Health Germany 507 GmbH
Cardinal Health Germany Manufacturing GmbH
Cardinal Health Global Contracting Company Limited
Cardinal Health Holding International, Inc.
Cardinal Health Holdings Hungary Kft.
Cardinal Health International India Pvt. Ltd.
Cardinal Health International Philippines, Inc.
Cardinal Health IPS, LLC
Cardinal Health Ireland 419 Designated Activity Company
Cardinal Health Ireland 508 Limited
Cardinal Health Ireland Manufacturing Limited
Cardinal Health Ireland Unlimited Company
Cardinal Health Italy 509 S.r.l.
Cardinal Health K.K.
Cardinal Health Korea Limited
Cardinal Health Luxembourg 522 S.a.r.l.
Cardinal Health Malaysia 211 Sdn. Bhd.
Cardinal Health Malta 212 Limited
Cardinal Health Managed Care Services, LLC
Cardinal Health Mexico 514 S. de R.L. de C.V.
Cardinal Health Middle East FZ-LLC
Cardinal Health MPB, Inc.
Cardinal Health Napoleon Holding, LLC
Cardinal Health Netherlands 502 B.V.
Cardinal Health Netherlands 525 Cooperatie U.A.

© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: 570000070825
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Cardinal Health, Inc.
POLICY NUMBER	
See Certificate Number: 570122321493	
CARRIER / NAIC CODE	EFFECTIVE DATE:
See Certificate Number: 570122321493	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 FORM TITLE: Certificate of Liability Insurance

Named Insureds Continued

Cardinal Health P.R. 120, Inc.
Cardinal Health P.R. 218, Inc.
Cardinal Health P.R. 220, LLC
Cardinal Health P.R. 436, Inc.
Cardinal Health Panama, S. de R.L.
Cardinal Health Pharmaceutical Contracting, LLC
Cardinal Health Pharmacy Services, LLC
Cardinal Health Regional Headquarters Company
Cardinal Health Singapore 225 Pte. Ltd.
Cardinal Health Spain 511 S.L.
Cardinal Health Switzerland 515, GmbH
Cardinal Health Systems, Inc.
Cardinal Health Technologies Switzerland GmbH
Cardinal Health Technologies, LLC
Cardinal Health U.K. 432 Limited
Cardinal Health U.K. International Holding LLP
Cardinal Health, Inc.
Cardinal MED Equipment Consulting (Shanghai) Co., Ltd.
Cirpro de Delicias S. de R.L. de C.V.
Clinic Pharmacies III, LLC
Clinic Pharmacies, LLC
Convertors de Mexico S. de R.L. de C.V.
Cordis Corporation
Cornerstone Rheumatology LP
3-101-587185 Sociedad Anonima
Dutch American Manufacturers II (D.A.M. II) B.V.
Ellipticare, LLC
EPIC Insurance Company
Especialidades Medicas Kenmex S. de R.L. de C.V.
Experience East, LLC
Flexible Stenting Solutions, LLC
GastroGPO, LLC
Gastrologix, LLC
Generic Drug Holdings, LLC
Griffin Capital, LLC
HDG Acquisition, LLC
imgRx Healdsburg, Inc.
imgRx Salud, Inc.
imgRx SJ Valley, Inc.
imgRx SLO, Inc.
imgRx Sonoma, Inc.
InnerDyne Holdings, Inc.
Innovative Therapies, LLC
Instant Diagnostic Systems, Inc.
InteCardia-Tennessee East Catheterization, LLC
ITI Sales, LLC
Kendall-Gammatron Limited
Killilea Development Company, Ltd.
Kinray I, LLC
KPR U.S., LLC
Leader Drugstores, Inc.
Ludlow Technical Products Canada, Ltd.

© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: 570000070825
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Cardinal Health, Inc.
POLICY NUMBER	
See Certificate Number: 570122321493	
CARRIER / NAIC CODE	EFFECTIVE DATE:
See Certificate Number: 570122321493	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Named Insureds Continued

Marin Apothecaries
Medicap Pharmacies Incorporated
Medicine Shoppe Capital Corporation
Medicine Shoppe International, Inc.
Medicine Shoppe Internet, Inc.
Mediquip Sdn. Bhd.
MosaicGPO, LLC
mscripts Holdings, LLC
mscripts, LLC
Nautic Specialty Networks VIII-A Bocker, LLC
Navista Investments, LLC
Navista Network Holding, LLC
Navista Network, LLC
North Coast Medical Supply, LLC DBA Advanced Diabetes Supply
One Cloverleaf, LLC
OptiFreight Logistics, LLC
Owen Shared Services, Inc.
Pharmacy Operations Of New York, Inc.
Pharmacy Operations, Inc.
Physicians Purchasing, Inc.
Pinnacle Intellectual Property Services, Inc.
Pinnacle Intellectual Property Services-International, Inc.
Precision Point Specialty, LLC
ProMed DME Holdings, LLC
ProMed DME, LLC
Quiroproductos de Cuauhtemoc S. de R.L. de C.V.
RainTree Administrative Services, LLC
RainTree Care Management, LLC
RainTree GPO, LLC
Red Oak Sourcing, LLC
Renal Purchasing Group, LLC
RGH Enterprises, LLC
RT Oncology Services Corporation
Rxealtime, Inc.
Sierra Radiopharmacy, L.L.C.
SN Buyer, LLC
SN Funding, LLC
SN Intermediate, Inc.
SOAR Network, LLC
Sonexus Health Access & Patient Support, LLC
Sonexus Health Distribution Services, LLC
Sonexus Health Financial Solutions, LLC
Sonexus Health Pharmacy Services, LLC
Sonexus Health, LLC
Specialty Networks Consulting, LLC
Specialty Networks Research, LLC
Specialty Networks Urology Registry, LLC
Specialty Networks, LLC
Strive Intermediate Holdco, LLC
Strive Acquisition, LLC
Strive Medical LLC
Strive Diabetes, Inc.
The Harvard Drug Group, L.L.C.
Traverse GPO, LLC
United Rheumatology NY IPA I, LLC
United Rheumatology, LLC
United States Medical Supply, LLC
US Med, LLC
United States Med Direct, LLC
UR Nice, LLC
UroGPO, LLC
US Med Buyer, LLC
US Med Acquisition, LLC
US Med Direct, LLC
Velocare, LLC
Wavemark Cyprus Pvt. Ltd.
Wavemark Lebanon Offshore s.a.l.
Wavemark, Inc.

© 2008 ACORD CORPORATION. All rights reserved.
The ACORD name and logo are registered marks of ACORD

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **STRIVE MEDICAL LLC** as a FOREIGN LIMITED-LIABILITY COMPANY duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 09/17/2012, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 08/03/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202608036868036
You may verify this certificate online at https://www.nvsilverflume.gov/home

CardinalHealth

5800 Campus Circle Drive E
Suite 100B
Irving, Texas 75063

Officer Name	Title	Company
Robert Evan Schlissberg	President	Strive Medical LLC
Keegan David Chamberlain	Director, Quality Management	Strive Medical LLC
John Henry Martin Jr.	SVP, Tax	Strive Medical LLC
Brent Mathew Withrow	Assistant Treasurer	Strive Medical LLC
Anthony F. Alvarez	Secretary	Strive Medical LLC

Copyright © 2026 Cardinal Health. All Rights Reserved.
The above information is confidential and to be used for licensing purposes only. Any other use is strictly prohibited without prior consent of Cardinal Health.

Attachment B

Post-Closing Officers
Strive Medical LLC

- Robert Schlissberg – President
- Keegan Chamberlain – Director, Regulatory Management
- John Martin Jr. – Senior Vice President, Tax
- Brent Withrow – Treasurer
- Anthony F. Alvarez – Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Strive Medical LLC — MDEG License # (if applicable): MP01308

Physical Address: 3111 S Valley View Blvd Suite B118

City: Las Vegas — State: NV — Zip: 89102

Mailing Address (if different from physical address): 5800 Campus Circle Drive E Suite 100B

City: Irving — State: TX — Zip: 75063

Telephone: 888-771-9229 — Website: www.strivemedical.com

Licensing Company Email: jrosenthal@strivemedical.com

Section 2: Personal Information

First: Angelina — Middle: Rosana — Last: Galindo

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: N las Vegas — State: NV — Zip: [redacted]

Telephone: [redacted] — Email: agalindo@strivemedical.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Western High School		09.90 to 06.93	
Address	City	State	Zip
4601 W Bonanza Rd	Las Vegas	NV	89107
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/17 to current	[redacted]	N LAS VEGAS	NV	[redacted]
From - To (MM/YY – MM/YY)	[redacted]	LAS VEGAS	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Strive Medical LLC			08/17/2014 to current	
Business Address		City	State	Zip
3111 S Valley View Blvd Suite B118		Las Vegas	NV	89102
Phone	Title		Number of Employed Hours	
888-771-9229	Wound Care Department Supervsior		1,500+	
Description of Duties				
Oversee the day to day operations of the wound care department. This includes leading a team through training and development to meet our goals and deliver excellent customer service.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # n/a . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

A. Galindo

Original Signature (electronic, copies or stamps not accepted)

07/22/2026

Date

I, Angelina Galindo, **certify that as the MDEG Administrator for**

Strive Medical LLC,

that I (initial that you have read and meet the following requirements):

1. AG Have a high school diploma or its equivalent;
2. AG Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. AG Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. AG Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Angelina, Galindo
Print Name (First, Last)

A Galindo
Original Signature (electronic, copies or stamps not accepted)

07/22/2026
Date

Board Use Only	Date Received: 8/5/26

Cardinal Health
7000 Cardinal Place
Dublin, OH 43017

CardinalHealth™

August 3, 2026

Dave Wuest
Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy
Reno, NV 89521

RE: Indirect Ownership Change of Strive Medical LLC
Medical Devices Equipment Gas License No. MP01308

Dear Madam or Sir,

On August 3, 2026, RGH Enterprises, LLC ("RGH") acquired 100% of the equity interests in Strive Intermediate Holdco, LLC. The acquisition closed on August 3, 2026 (the "Closing"). As a result of the Closing, RGH became the great-grandparent owner of Strive Medical LLC. We have enclosed pre- and post-Closing organizational charts as Attachment A. Notwithstanding the Closing, Strive Medical LLC's name, address, direct ownership, federal tax identification number, locations, and day-to-day operations remain unchanged.

Additionally, effective as of the Closing, there are changes to Strive Medical LLC's officers. We have enclosed a post-Closing officer list as Attachment B.

The Closing involves only an indirect ownership change at an upper tier of the ownership chain and Strive Medical LLC will continue as the license holder, attached is a new application. Please contact me immediately at licensure@cardinalhealth.com if you have any questions.

Sincerely,

Keegan Chamberlain
Director of Quality and Regulatory Affairs

Enclosures (3):
Application
Attachment A (Pre- and Post-Closing Legal Entity Structures)
Attachment B (Post-Closing Officers)

8D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☑ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	☑ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		MDEG Business Type (check applicable box)
☑ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☑ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M NA	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Tag 2 Collaboration LLC.

MDEG Physical Address: 5860 Wynn Rd Ste. B

City: Las Vegas State: NV Zip: 89118

Mailing Address (if different from physical address): SAME

City: _____ State: _____ Zip: _____

Telephone: 732-515-5511 Website: _____

Email: [redacted]

Name of MDEG Administrator (NAC 639.694): Jack Mader

Entities the MDEG will Serve	Type of MDEG products that will be sold (check all applicable)
☑ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☑ Assistive Equipment
☐ Wholesalers[a]	☑ Diabetic Supplies
☐ Other business entities (specify)[a]:	☑ Orthotics and Prosthetics
	☑ Others: Mobility devices
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: NA
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
▣ Mon: 9am-3pm	▣ Tue: 9am-3pm	▣ Wed: 9am-3pm	▣ Thurs: 9am-3pm	▣ Fri: 9am-3pm
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Medicare PTAN 7706190001

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: NA Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: NA

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: na

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Partnership

Partnership Name: Tag 2 Collaboration

Mailing Address: 5860 Wynn Rd Ste B

City: Las Vegas State: NV Zip: 89118

Telephone: [redacted] Email: [redacted]

Contact Person Name: Jack Mader

Section 8: Sole Owner

Owner's Name: NA

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jack Mader

Print Name of Authorized Person Submitting Application

Jack Mader

Original signature of Authorized Person (copies or stamps not accepted)

4/7/26

Date

Board Use Only	Date Received: 4/20/26	Amount: $500.00

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 4/10/2026

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER: VGM Insurance Services, Inc. 1111 Van Miller Way Waterloo IA 50701	CONTACT NAME: Michelle Newman PHONE (A/C, No, Ext): (800) 507-5736 FAX (A/C, No): E-MAIL ADDRESS: Michelle.Newman@vgm.com
INSURED: TAG 2 Collaboration LLC 5860 Wynn Rd Suite #B Las Vegas NV 89118	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : BENCHMARK INSURANCE COMPANY — 41394 INSURER B : INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			D1025 G7601-1	03/13/2026	03/13/2027	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
	X Professional Liability						MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 3,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 3,000,000
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	ALL OWNED AUTOS / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS / NON-OWNED AUTOS						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N / A (Mandatory in NH)						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

National Provider Enrollment West (NPWest)
Palmetto GBA, AG-495
P.O. Box 100142
Columbia SC 29202

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

© 1988-2014 ACORD CORPORATION. All rights reserved.

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **TAG 2 Collaboration LLC** as a FOREIGN LIMITED-LIABILITY COMPANY duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 03/30/2026, and in good standing in this State.

I further certify that the above FOREIGN LIMITED-LIABILITY COMPANY has its formation or qualification document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 05/21/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202605216696039
You may verify this certificate online at https://www.nvsilverflume.gov/home

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Annual or Amended List and State Business License Application - Continued

Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

CORPORATION, INDICATE THE Member:

Name	Country
Jack Mader	USA

Address	City	State	Zip/Postal Code
5860 Wynn Rd Suite B	Las Vegas	NV	89118

CORPORATION, INDICATE THE Member:

Name	Country
Gevork Najarian	USA

Address	City	State	Zip/Postal Code
5860 Wynn Road Ste B	Las Vegas	NV	89118

None of the officers and directors identified in the list of officers has been identified with the fraudulent intent of concealing the identity of any person or persons exercising the power or authority of an officer or director in furtherance of any unlawful conduct.

I declare, to the best of my knowledge under penalty of perjury, that the information contained herein is correct and acknowledge that pursuant to NRS 239.330, it is a category C felony to knowingly offer any false or forged instrument for filing in the Office of the Secretary of State.

X Jack Mader

Signature of Officer, Manager, Managing Member, General Partner, Managing Partner, Trustee, Subscriber, Member, Owner of Business, Partner or Authorized Signer *FORM WILL BE RETURNED IF UNSIGNED*

Member	04/01/2026
Title	Date

FRANCISCO V. AGUILAR
Secretary of State
401 North Carson Street
Carson City, Nevada 89701-4201
(775) 684-5708
Website: www.nvsos.gov
www.nvsilverflume.gov

Annual or Amended List and State Business License Application

☐ ANNUAL ☑ AMENDED (check one)

List of Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers:

TAG 2 Collaboration LLC
NAME OF ENTITY

NV20263552784
Entity or Nevada Business Identification Number (NVID)

TYPE OR PRINT ONLY - USE DARK INK ONLY - DO NOT HIGHLIGHT

IMPORTANT: *Read instructions before completing and returning this form.*

Please indicate the entity type (check only one):

☐ Corporation
☐ This corporation is publicly traded, the Central Index Key number is:

☐ Nonprofit Corporation (see nonprofit sections below)

☑ Limited-Liability Company

☐ Limited Partnership

☐ Limited-Liability Partnership

☐ Limited-Liability Limited Partnership

☐ Business Trust

☐ Corporation Sole

Filed in the Office of	Business Number
FVAguilar	**E56303972026-1**
	Filing Number
	20265641202
Secretary of State	Filed On
State Of Nevada	**04/01/2026 13:19:34 PM**
	Number of Pages
	2

Additional Officers, Managers, Members, General Partners, Managing Partners, Trustees or Subscribers, may be listed on a supplemental page.

CHECK ONLY IF APPLICABLE

Pursuant to NRS Chapter 76, this entity is exempt from the business license fee.
☐ 001 - Governmental Entity
☐ 006 - NRS 680B.020 Insurance Co, provide license or certificate of authority number

For nonprofit entities formed under NRS chapter 80: entities without 501(c) nonprofit designation are required to maintain a state business license, the fee is $200.00. Those claiming an exemption under 501(c) designation must indicate by checking box below.

☐ Pursuant to NRS Chapter 76, this entity is a 501(c) nonprofit entity and is exempt from the business license fee. Exemption Code 002

For nonprofit entities formed under NRS Chapter 81: entities which are Unit-owners' association or Religious, Charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C $ 501(c) are excluded from the requirement to obtain a state business license. Please indicate below if this entity falls under one of these categories by marking the appropriate box. If the entity does not fall under either of these categories please submit $200.00 for the state business license.

☐ Unit-owners' Association ☐ Religious, charitable, fraternal or other organization that qualifies as a tax-exempt organization pursuant to 26 U.S.C. $501(c)

For nonprofit entities formed under NRS Chapter 82 and 80:Charitable Solicitation Information - check applicable box

Does the Organization intend to solicit charitable or tax deductible contributions?

☐ No - no additional form is required
☐ Yes - the "Charitable Solicitation Registration Statement" is required.
☐ The Organization claims exemption pursuant to NRS 82A 210 - the "Exemption From Charitable Solicitation Registration Statement" is required

****Failure to include the required statement form will result in rejection of the filing and could result in late fees.****

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: TAG 2 Collaboration LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): NA

Physical Address: 5860 Wynn Rd Ste B

City: Las Vegas State: NV Zip: 89118

Mailing Address (if different from physical address): SAME

City: State: Zip:

Telephone: 732-515-5511 Website:

Licensing Company Email: [redacted]

Section 2: Personal Information

First: Gevork Middle: George Last: Najarian

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Van Nuys State: CA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
City of Angels		(01/20-05/22)	
Address	City	State	Zip
13000 Hart St	North Hollywood	CA	91605
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
West Coast University			
Address	City	State	Zip
12215 Victory Blvd	, North Hollywood	CA	91606
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/12-04/26	[redacted]	Van Nuys	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Loyalty Auto Group			03/23-04/26
Business Address	**City**	**State**	**Zip**
1605 Victory Blvd	Glendale	CA	91201
Phone	**Title**		
818-200-0333	Auto Broker		
Description of Duties			
Middle man between car dealership and client, work with fleet managers to get better deals on lease/financed cars for our clients.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gevork George Najarian

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/03/2026

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Gevork George Najarian, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

04/09/2026

Date

Subscribed and Sworn to before me this 9th day of April 2026.

Christopher Manvelyan Notary officer

Notary Public Signature

CHRISTOPHER DAVID MANVELYAN
COMM. # 2454634
NOTARY PUBLIC • CALIFORNIA
LOS ANGELES COUNTY
My Comm. Expires JULY 23, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: TAG 2 Collaboration LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): NA

Physical Address: 5860 Wynn Rd Ste B

City: Las Vegas State: NV Zip: 89118

Mailing Address (if different from physical address): SAME

City: State: Zip:

Telephone: 732-515-5511 Website:

Licensing Company Email:

Section 2: Personal Information

First: Jack Middle: Harrison Last: Mader

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: tallahasee State: fl Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Chiles High School			
Address	**City**	**State**	**Zip**
7200 Lawton Chiles Ln	Tallahassee	FL	32312
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
(01-18 - 04-26)	[redacted]	Tallahassee	FL	[redacted]
From - To (MM/YY – MM/YY)		City	State	
(04-12 - 01-18)		Tallahassee	FL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
U.S. Army			(07/18 - present)
Business Address	**City**	**State**	**Zip**
Office of the Secretary of the Army	Washington	DC	20310
Phone	**Title**		
1 (888) 332-7411	Soldier		
Description of Duties			
War fighter			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jack, Mader

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/06/2026

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Orange

I, Jack Harrison Mader, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

04/06/2026

Date

Subscribed and Sworn to before me this 6 day of April 2026.

Notary Public Signature

SAMANDA D MCDONALD
Notary Public - State of New York
NO. 01MC6443069
Qualified in Dutchess County
My Commission Expires Oct 24, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Tag 2 Collaboration LLC MDEG License # (if applicable) Pending

Physical Address 5866 Wynn RD STE B1

City Las Vegas State NV Zip 89118

Mailing Address (if different from physical address)

City State Zip

Telephone 950-755-0669 Website GetNEXUSDME.com

Licensing Company Email www.GETNEXUSDME.com → Info@getnexusdme.com

Section 2: Personal Information

First Carlos Middle Miguel Last Mandapat

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Cimarron Memorial High School		08/01 - 06/05	
Address	**City**	**State**	**Zip**
2301 N. Tenaya Way	Las Vegas	NV	89128
Diploma/Degree obtained, if any			
High school Degree w/honors			

School Name		From - To (MM/YY – MM/YY)	
College of Southern Nevada		08/05 - 06/07	
Address	**City**	**State**	**Zip**
6375 W. Charleston Blvd.	Las Vegas	NV	89128
Diploma/Degree obtained, if any			
some college NO degree			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/17 - 06/26	[redacted]	LAS VEGAS	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Tag 2 collaborations LLC		08/25 - 7/26	
Business Address	**City**	**State**	**Zip**
5860 Wynn RD STE B	Las Vegas	NV	89118
Phone	**Title**	**Number of Employed Hours**	
732-515-5511	Office Administrator	1700+	
Description of Duties			
Answering emails & phone calls for the company and regular office duties.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, Carlos Mandapat, **certify that as the MDEG Administrator for** Tag 2 Collaboration,

that I (initial that you have read and meet the following requirements):

1. CM Have a high school diploma or its equivalent;
2. CM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Carlos Mandapat

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

July 24, 26

Date

Board Use Only	Date Received: 8/5/26

9

9A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada	☑ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☑ Dangerous drugs
	☐ Location Change *	☐ Internet	☑ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☑ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: CUR8 PHARMACY

Physical Address: 2510 Wigwam Parkway, Suite 207

City: Henderson State: NV Zip: 89074

Mailing Address (if different from physical address): 9075 S. EASTERN AVE, SUITE 6-114

City. LAS VEGAS State: NV Zip: 89123

Telephone: (702) 460-4364 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: _____ Contact Email: HELLO@CUR8RX.COM

Website: CUR8RX.COM

Nevada Business License # (if applicable) NV20253479713

Supervising/Managing Pharmacist Name (NRS 639.220): IVO MIRTCHEV

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 18766

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: IVO MIRTCHEV	NV Pharmacist Registration #: 18766
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials: NA	%: NA
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: NA

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NEVADA

Parent Company (if any): _____

Corporation/Organization Name: CUR8 PHARMACY LLC

Mailing Address: 9075 S EASTERN AVE, SUITE 6-114

City: LAS VEGAS State: NV Zip: 89123

Telephone: (702) 460-4364 Email: HELLO@CUR8RX.COM

Contact Person Name: IVO MIRTCHEV

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: NA

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: NA

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the MANAGING PHARMACIST (title) for CUR8 PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

IVO MIRTCHEV

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

05/26/26

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, IVO MIRTCHEV hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the MANAGING PHARMACIST (title) for CUR8 PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 26th day of May, 2026

Mandip Kaur
Notary Public

Notary Public - State of Nevada
COUNTY OF CLARK
MANDIP KAUR
My Appointment Expires
FEBRUARY 20, 2027
No. 23-7466-01

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: IVO MIRTCHEV Pharmacist Registration #: 18766

Pharmacy Name: CUR8 PHARMACY

Initial each statement below to indicate you have read and agree with the following:

IM IM I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

IM IM I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

IM IM I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

IM IM I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

IM IM I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

05/26/26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

IVO MIRTCHEV

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

05/26/26

Date

Board Use Only	Date Received: 5/28/26	Amount: $500 CK 1118

Nevada State Board of Pharmacy
Pharmacy Application — Cur8 Pharmacy
Section 12 — Requested Documents Appendix

Cur8 Pharmacy Business Type: Non-Publicly Traded (specifically a Manager-managed LLC)

Section 12: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	**Non-publicly Traded**	**Cur8 Pharmacy Comments**
List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)	✓	Ivo Mirtchev - Manager / Managing Pharmacist, Co-owner Marianne Mirtchev - Co-owner
List the top four stockholders and their percent ownership. NRS 639.231(3)	✓	Ivo Mirtchev - 51% Marianne Mirtchev - 49%
List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)	✓	Ivo Mirtchev - 51% Marianne Mirtchev - 49%
Certificate of Corporate Status or Certificate of Good Standing from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**.	✓	Refer to attached Certificate of Good Standing
Designated Representative Form http://bop.nv.gov/Services/newapps/Business/ must be completed by the Designated Representative. NAC 639.5005. The requirement does not apply to: a. An applicant or a licensee that is a publicly traded corporation; b. An applicant or licensee whose pharmacy is determined by the Board to be located within a large retail store, including, without limitation, a grocery store, variety store or department store under common ownership; or c. An applicant or licenses in which a majority interest of the applicant or licensee is owned by a pharmacist who is: 1) License by the Board; and 2) A resident of this state.	✓	Not Applicable - Condition C applies. Majority interest is owned by a pharmacist (Ivo Mirtchev) who is licensed by the Board and a resident of Nevada
Personal History Record Application http://bop.nv.gov/Services/newapps/Business/ must be completed by: **a. For Non-publicly traded** - The top 4 shareholder/stockholders. **b. For Partnerships** - All general partners; all limited partners who hold 10% or more of the interest. **c. For Sole Owner** - The owner.	✓	Refer to attached Personal History Record Application completed by: - Ivo Mirtchev - Marianne Mirtchev
Sterile Compounding Questionnaire must be completed if the pharmacy will provide sterile compounded drugs. Access form at http://bop.nv.gov/Services/newapps/Business/.	✓	Not Applicable - sterile compounding will not be conducted
Submit a copy of your most recent pharmacy inspection from the regulatory or licensing authority of the state, territory or Federal agency in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(f)	✓	Not Applicable - newly established pharmacy solely based in Nevada
Submit a copy of your license, certification, permit or registration issued to your pharmacy from the regulatory board or licensing authority of the state or territory in which the pharmacy is located. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2328(2)(a)	✓	Not Applicable - newly established pharmacy solely based in Nevada

Section 12: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Non-publicly Traded	Cur8 Pharmacy Comments
License Verification by the regulatory board or licensing authority of the state or territory in which the pharmacy is located. You may use the License Verification form here: http://bop.nv.gov/Services/newapps/Business/. **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)** NRS 639.2238(2)(g)	✓	Not Applicable - newly established pharmacy solely based in Nevada
Copy of DEA Registration if the pharmacy will be handling or dispensing controlled substances **(REQUIRED FOR NON-NEVADA PHARMACIES ONLY)**	✓	Not Applicable - newly established pharmacy solely based in Nevada
Internet Pharmacy Services Certification (REQUIRED FOR PHARMACIES PROVIDING INTERNET PHARMACY SERVICES)	✓	Not Applicable - internet pharmacy services will not be conducted
Transmit Controlled Substance Prescription Data- Pharmacies dispensing scheduled II-V controlled substance for human consumption shall, not later than the end of the next business day after dispensing a controlled substance, upload to the Nevada Prescription Monitoring Program (PMP) the information described in paragraph (d) of subsection 1 of NRS 453.162. Registration information found at: https://bop.nv.gov/links/PMP/	✓	Requirement acknowledged

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Cur8 Pharmacy LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 11/19/2025, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 05/26/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202605266702113
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: CUR8 PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A - NEW APPLICANT

Physical Address: TBD - LOCATION SCOUTING / LEASE NOT YET FINALIZED

City: _____ State: _____ Zip: _____

Mailing Address (if different from physical address): 9075 S. EASTERN AVE, SUITE 6-114

City: LAS VEGAS State: NV Zip: 89123

Telephone: (702) 460-4364 Website: CUR8RX.COM

Licensing Company Email: HELLO@CUR8RX.COM

Section 2: Personal Information

First: IVO Middle: _____ Last: MIRTCHEV

Alias(es, nicknames, name changes, etc.): IVO TZVETISLAVOV MIRTCHEV

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: LAS VEGAS State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
ROSEMAN UNIVERSITY		05/11 - 05/14	
Address	**City**	**State**	**Zip**
11 SUNSET WAY	HENDERSON	NV	89014
Diploma/Degree obtained, if any			
DOCTOR OF PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF NEVADA, LAS VEGAS		08/07 - 05/11	
Address	**City**	**State**	**Zip**
4505 S. MARYLAND PKWY	LAS VEGAS	NV	89154
Diploma/Degree obtained, if any			
BACHELOR OF SCIENCE - BIOLOGY			

School Name		From - To (MM/YY – MM/YY)	
SILVERADO HIGH SCHOOL		08/03 - 05/07	
Address	**City**	**State**	**Zip**
1650 SILVER HAWK AVE	LAS VEGAS	NV	89123
Diploma/Degree obtained, if any			
HONORS HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
N/A - BLANK			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A - BLANK			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/17 - PRESENT	[redacted]	LAS VEGAS	NV	[redacted]
01/16 - 02/17	[redacted]	SEATTLE	WA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
SMITH'S PHARMACY (KROGER)			05/19 - PRESENT	
Business Address	**City**	**State**	**Zip**	
4840 W DESERT INN RD	LAS VEGAS	NV	89102	
Phone	**Title**			
702 - 248 - 1854	PHARMACY MANAGER / PHARMACIST			
Description of Duties				
FULL DUTIES AS PHARMACY MANAGER INCLUDING DISPENSING, COUNSELING, AND VACCINATIONS.				

Business Name			From - To (MM/YY – MM/YY)	
SYNTHESIS RESEARCH LLC			08/24 - 5/25	
Business Address	**City**	**State**	**Zip**	
8565 S EASTERN AVE	LAS VEGAS	NV	89123	
Phone	**Title**			
N/A	CO-OWNER			
Description of Duties				
ONLINE SUPPLEMENT BUSINESS, DISSOLVED BEFORE OPENING.				

Business Name			From - To (MM/YY – MM/YY)	
SMITH'S PHARMACY (KROGER)			03/17 - 05/19	
Business Address	**City**	**State**	**Zip**	
VARIOUS	LAS VEGAS	NV	89102	
Phone	**Title**			
N/A	STAFF PHARMACIST			
Description of Duties				
WORKED AS STAFF PHARMACIST AT VARIOUS SMITH'S LOCATIONS IN THE GREATER LAS VEGAS, HENDERSON, & PAHRUMP AREAS. FULL DUTIES INCLUDING DISPENSING, COUNSELING, AND VACCINATIONS.				

Business Name			From - To (MM/YY – MM/YY)	
FRED MEYER PHARMACY (KROGER)			06/15 - 02/17	
Business Address	**City**	**State**	**Zip**	
6901 S 19TH ST	TACOMA	WA	98466	
Phone	**Title**			
253 - 564 - 7477	STAFF PHARMACIST			
Description of Duties				
FULL STAFF PHARMACIST DUTIES INCLUDING DISPENSING, COUNSELING, VACCINATIONS, AND PRESCRIBING VIA COLLABORATIVE PRACTICE AGREEMENT.				

Business Name			From - To (MM/YY – MM/YY)	
N/A - BLANK				
Business Address	**City**	**State**	**Zip**	
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
N/A - BLANK			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A - BLANK			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A - BLANK			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A - BLANK			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A - BLANK			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

05/26/26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

IVO MIRTCHEV

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05/26/26

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Ivo Mirtchev, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

05/26/26

Date

Subscribed and Sworn to before me this 26th day of May, 2026.

Mandip Kaur

Notary Public Signature

Notary Public - State of Nevada
COUNTY OF CLARK
MANDIP KAUR
My Appointment Expires
FEBRUARY 20, 2027
No. 23-7466-01

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site CUR8 PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) N/A - NEW APPLICANT

Physical Address TBD - LOCATION SCOUTING / LEASE NOT YET FINALIZED

City _____ State _____ Zip _____

Mailing Address (if different from physical address) 9075 S. EASTERN AVE, SUITE 6-114

City LAS VEGAS State NV Zip 89123

Telephone (702) 460-4364 Website CUR8RX.COM

Licensing Company Email HELLO@CUR8RX.COM

Section 2: Personal Information

First MARIANNE Middle _____ Last MIRTCHEV

Alias(es, nicknames, name changes, etc.) MARIANNE SEGISMUNDO

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Addres [redacted]

City LAS VEGAS State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
UNIVERSITY OF NEVADA, LAS VEGAS			08/07 - 05/12	
Address		**City**	**State**	**Zip**
4505 S. MARYLAND PKWY		LAS VEGAS	NV	89154
Diploma/Degree obtained, if any				
MASTER OF SCIENCE - ACCOUNTING, BACHELOR OF SCIENCE IN BUSINESS ADMINISTRATION - ACCOUNTING				
School Name			From - To (MM/YY – MM/YY)	
SILVERADO HIGH SCHOOL			08/04 - 05/07	
Address		**City**	**State**	**Zip**
1650 SILVER HAWK AVE		LAS VEGAS	NV	89123
Diploma/Degree obtained, if any				
HONORS HIGH SCHOOL DIPLOMA				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/17 - PRESENT	[redacted]	LAS VEGAS	NV	[redacted]
01/16 - 02/17	[redacted]	SEATTLE	WA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Business Name			From - To (MM/YY – MM/YY)
N/A - BLANK			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A - BLANK			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A - BLANK			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A - BLANK			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A - BLANK			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

05/26/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

MARIANNE MIRTCHEV

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05/26/26

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Marianne Mirtchev, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

05/26/2026

Date

Subscribed and Sworn to before me this 26th day of May, 2026.

Mandip Kaur

Notary Public Signature

Notary Public - State of Nevada
COUNTY OF CLARK
MANDIP KAUR
My Appointment Expires
FEBRUARY 20, 2027
No. 23-7466-01

(Seal)

9B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada	☐ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☐ Out-of-Nevada	☒ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: [redacted]
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 02657		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: DOLCRX

Physical Address: 6820 W CHEYENNE AVE

City: LAS VEGAS State: NV Zip: 89108

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 7024365279 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 7027768201 Contact Email: HECTOR@DOLCRX.COM

Website: WWW.DOLCRX.COM

Nevada Business License # (if applicable) NV20191408499

Supervising/Managing Pharmacist Name (NRS 639.220): HECTOR DELEON

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 19970

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: HECTOR DELEON	NV Pharmacist Registration #: 19970
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: n/a	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NEVADA

Parent Company (if any): _____

Corporation/Organization Name: DOLCRX LLC

Mailing Address: 6820 W CHEYENNE AVE

City: LAS VEGAS State: NV Zip: 89108

Telephone: 7024365279 Email: HECTOR@DOLCRX.COM

Contact Person Name: HECTOR DELEON

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the PHARMACIST (title) for DOLCRX (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

HECTOR DELEON

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

8/29/26

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, HECTOR DELEON hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the PHARMACIST (title) for DOLCRX (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Hector DeLeon
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 29 day of August, 20 26

Notary Public

ALBERT LORENZANA
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 04-02-28
Certificate No: 24-6162-01

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: HECTOR DELEON Pharmacist Registration #: 19970

Pharmacy Name: DOLCRX

Initial each statement below to indicate you have read and agree with the following:

HD	I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.
HD	I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.
HD	I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.
HD	I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).
HD	I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✔

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hector DeLeon 8/29/26

Original signature of Managing Pharmacist (copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

HECTOR DELEON

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Hector DeLeon

Original signature of Authorized Person (copies or stamps not accepted)

8/29/26

Date

Board Use Only	Date Received: 9/11/26	Amount: $500 ck 1684

8/29/26

To Whom It May Concern:

Once the ownership transfer is approved by the Nevada State Board of Pharmacy, I will assume 100% ownership of DOLCRX and will be the sole owner of the company.

Sincerely,

Hector DeLeon
Prospective Owner / Buyer

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **DOLCRX, LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 05/31/2019, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 08/28/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202608286922107
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site DOLCRX PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH02657

Physical Address 6820 W CHEYENNE AVE

City LAS VEGAS State NV Zip 89108

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-436-5279 Website WWW.DOLCRX.COM

Licensing Company Email INFO@DOLCRX.COM

Section 2: Personal Information

First HECTOR Middle ALEJANDRO Last DELEON

Alias(es, nicknames, name changes, etc.) ALEX

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City NORTH LAS VEGAS State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
ROSEMAN UNIVERSITY OF HEALTH SCIENCES		08/15 - 05/18	
Address	**City**	**State**	**Zip**
11 SUNSET WAY	HENDERSON	NV	89014
Diploma/Degree obtained, if any			
DOCTORATE OF PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF NEVADA, LAS VEGAS		08/10 - 05/15	
Address	**City**	**State**	**Zip**
4505 S MARYLAND PKWY	LAS VEGAS	NV	89154
Diploma/Degree obtained, if any			
BACHELORS OF SCIENCE OF BIOLOGY			

School Name		From - To (MM/YY – MM/YY)	
RANCHO HIGH SCHOOL		08/16 - 05/10	
Address	**City**	**State**	**Zip**
1900 SEARLES AVE	LAS VEGAS	NV	89101
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/08 - PRESENT	[redacted]	LAS VEGAS	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
DOLCRX PHARMACY			11/18 - PRESENT	
Business Address	**City**	**State**	**Zip**	
6820 W CHEYENNE AVE	LAS VEGAS	NV	89108	
Phone	**Title**			
702-436-5279	PHARMACIST MANAGER			
Description of Duties				
PIC, MANAGING EMPLOYEES AND OPERATIONS, DATA ENTRY, MAINTAINING INVENTORY, ORDERING, DISPENSING, VERIFYING, AND COUNSELING PRESCRIPTIONS.				

Business Name			From - To (MM/YY – MM/YY)	
SMITH'S PHARMACY #376			06/17 - 05/18	
Business Address	**City**	**State**	**Zip**	
2385 E WINDMILL LN	LAS VEGAS	NV	89123	
Phone	**Title**			
702-837-0813	INTERN			
Description of Duties				
IMMUNIZATIONS, DATA ENTRY, FILLING, AND COUNSELING PRESCRIPTIONS.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**	
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**	
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**	
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8/29/26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

HECTOR DELEON

Print Name (First, Last)

Hector DeLeon

Original Signature (electronic, copies or stamps not accepted)

8/29/26

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Hector. DeLeon, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Hector DeLeon

Original Signature

8/29/26

Date

Subscribed and Sworn to before me this 29 day of August, 2026.

Notary Public Signature

ALBERT LORENZANA
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 04-02-28
Certificate No: 24-6162-01

(Seal)

9C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada	☑ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☑ Dangerous drugs
	☐ Location Change *	☐ Internet	☑ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☑ Non-sterile Compounding
			☑ Sterile Compounding
			☑ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH_____		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Meta Pharmacy Services

Physical Address: 500 Pilot Road, Suite A

City: Las Vegas State: NV Zip: 89119

Mailing Address (if different from physical address): 500 Pilot Road, Suite A

City: Las Vegas State: NV Zip: 89199

Telephone: (702) 356-3597 Toll Free # (NAC 639.708, NRS 639.23286): (888) 232-4065

Fax: (702) 754-6996 Contact Email: admin@metapharmacyservices.com

Website: www.metapharmacyservices.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Dino Dzanic

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20718

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Dino Dzanic	NV Pharmacist Registration #: 20718
Name: Jenner Sinang	NV Pharmacist Registration #: 18954
Name: Tommy Dinh	NV Pharmacist Registration #: 20256
Name: Maile Olah	NV Pharmacist Registration #: 19841
Name: Christopher Goodman	NV Pharmacist Registration #: 16422
Name: Joe Brown	NV Pharmacist Registration #: 24184
Name: Sin Cheung	NV Pharmacist Registration #: 19397
Name: Justin Ji	NV Pharmacist Registration #: 20624
Name: Thai Vo	NV Pharmacist Registration #: 17678
Name: Andrew Roth	NV Pharmacist Registration #: 17385

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A-Not Applicable	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A-Not Applicable

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): OGB Meta III, LLC

Corporation/Organization Name: Meta Pharmacy Las Vegas, LLC

Mailing Address: 1015 Atlantic Blvd, Suite 433

City: Atlantic Beach State: FL Zip: 32233

Telephone: (917) 288-7585 Email: derek@jbncp.com

Contact Person Name: Derek O'Leary

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: N/A-Not Applicable

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A-Not Applicable

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Vice President and Secretary (title) for Meta Pharmacy Services (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Andrew M. Vukadinovich

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

8/17/2026

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Dino Dzanic Pharmacist Registration #: 20718

Pharmacy Name: Meta Pharmacy Services

Initial each statement below to indicate you have read and agree with the following:

I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

8/14/26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew M. Vukadinovich

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

8/17/2026

Date

Board Use Only	Date Received: 8/25/26	Amount: $ 500 CC

Meta Pharmacy Las Vegas, LLC - Owners and Officers*

Name and Title	Business Address and Telephone	Home Address and Telephone	Ownership %
OGB Meta III, LLC Parent / Sole Member	1015 Atlantic Blvd, Suite 433 Atlantic Beach, FL 32233 (917) 288-7585 derek@jbncp.com	[redacted] Atlantic Beach, FL [redacted]	100%
Derek D. O'Leary President and Treasurer	1015 Atlantic Blvd, Suite 433 Atlantic Beach, FL 32233 (917) 288-7585 derek@jbncp.com	[redacted] Atlantic Beach, FL, [redacted]	0%
Andrew M. Vukadinovich[1] Vice President and Secretary	8352 West Warm Springs Road, Suite 120 Las Vegas, NV 89113-3629 (702) 754-0172 avukadinovich@metapharmacyservices.com	[redacted] Las Vegas, NV [redacted]	23.3% (Indirect)

* Entity Member Managed. No Managers

[1]License / Registration

State	Type	Number	Expiration
Florida	Registered Pharmacy Technician	RPT67348	12/31/2026

State of Florida
Department of State

I certify from the records of this office that META PHARMACY LAS VEGAS, LLC is a limited liability company organized under the laws of the State of Florida, filed on July 14, 2026.

The document number of this limited liability company is L26000369232.

I further certify that said limited liability company has paid all fees and penalties due this office through December 31, 2026 and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twelfth day of August, 2026

Secretary of State

Tracking Number: 8759039550CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Meta Pharmacy Services

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 500 Pilot Road, Suite A

City: Las Vegas State: NV Zip: 89119

Mailing Address (if different from physical address): 500 Pilot Road, Suite A

City: Las Vegas State: NV Zip: 89119

Telephone: (702) 356-3597 Website: www.metapharmacyservices.com

Licensing Company Email: admin@metapharmacyservices.com

Section 2: Personal Information

First: Dino Middle: Last: Dzanic

Alias(es, nicknames, name changes, etc.): N/A-Not Applicable

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Roseman University			08/17 to 5/20
Address	**City**	**State**	**Zip**
11 Sunset Way	Henderson	NV	89014
Diploma/Degree obtained, if any			
PharmD			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
7/26 to Current	[redacted]	Las Vegas	NV	[redacted]
2021 - 2026	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Meta Pharmacy Services			10/25-Present	
Business Address	**City**		**State**	**Zip**
8352 West Warm Springs Road, Suite 120,	Las Vegas		NV	89113
Phone	**Title**		**Number of Employed Hours**	
(702) 754-0172	Pharmacist-in-Charge		Approximately 2,000	
Description of Duties				
Manage and supervise licensed pharmacy in compliance with all Federal, State and local rules, regulations and company policies.				

Business Name			From - To (MM/YY – MM/YY)	
Meta Pharmacy Services			07/25-10/25	
Business Address	**City**		**State**	**Zip**
8352 West Warm Springs Road, Suite 120	Las Vegas,		NV	89113
Phone	**Title**		**Number of Employed Hours**	
(702) 754-0172	Staff Pharmacist		Approximately 700	
Description of Duties				
Verifying scripts, counseling patients, verifying compounds including SOPs, processes and formulas, compounding NS products, preforming DURs				

Business Name			From - To (MM/YY – MM/YY)	
Aeva Pharmacy			08/21-09/26	
Business Address	**City**		**State**	**Zip**
4641 Blue Diamond Road	Las Vegas,		NV	89139
Phone	**Title**		**Number of Employed Hours**	
(702) 558-2382	Staff Pharmacist		Approximately 9,000	
Description of Duties				
Verifying scripts, counseling patients, verifying compounds including SOPs, processes and formulas, compounding NS products, administering vaccines, preforming DURs				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

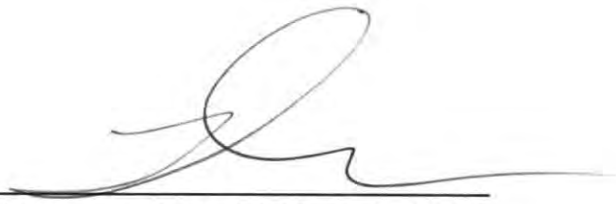
Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge N/A-Not Applicable				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

8/14/26

Date

I, Dino Dzanic, certify that as the designated representative for Meta Pharmacy Services,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Dino Dzanic

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/14/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dino Dzanic
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/14/26
Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Dino Dzanic, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/14/26
Date

Subscribed and Sworn to before me this 17th day of August 2026.

Misty Richardson
Notary Public Signature

MISTY DAWN RICHARDSON
Notary Public, State of Nevada
Appointment No. 24-1238-01
My Appt. Expires Mar 14, 2028
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Meta Pharmacy Services

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 500 Pilot Road, Suite A

City: Las Vegas State: NV Zip: 89119

Mailing Address (if different from physical address): 500 Pilot Road, Suite A

City: Las Vegas State: NV Zip: 89119

Telephone: (702) 356-3597 Toll Free # (NAC 639.708, NRS 639.23286): (888) 232-4065

Fax: (702) 754-6996 Contact Email: admin@metapharmacyservices.com

Website: www.metapharmacyservices.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Dino Dzanic

Supervising/Managing Pharmacist NV Pharmacist Registration #: 20718

Name of Designated Person(s) as defined by revised USP-797 guidelines: Dino Dzanic

Email of Designated Person(s): ddzanic@metapharmacyservices.com

Telephone of Designated Person(s): (702) 927-5324

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ☑ Category 2 ☑ Category 3

If you marked "**Category 3**", you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☑ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☑ Aseptic ☑ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ☑ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? N/A, new facility, not cerified yet

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ☐ No
N/A, new facility

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ☑ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Cat 3 compounding will be done so Cat 3 requirements will be follow even when Cat 2 compounding performed. SS performed weekly + DCA w each Cat 3 batch.

10. Will you be performing sterile hazardous drug compounding? ✓ Yes No

If you marked "**Yes**", you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

NAD+ Injection, Glutathione Injection, Methylcobalamin Injection, Sermorelin Injection, Semaglutide/Pyridoxine Injection, Semaglutide/Carnitine Injection, Tirzepatide/Pyridoxine Injection, Tirzepatide/Carnitine Injection, Testosterone/Zinc Injection, B-Complex Injection, Estriol Injection, Estradiol Injection, Trimix injections

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL

Address: 840 Research Parkway, Ste. 546

City: Oklahoma City State: OK Zip: 73104

Telephone: 800-393-1595

13. What is your procedure for visual inspection of compounded sterile products?

Each compounded sterile preparation (CSP) is visually inspected upon completion of compounding and prior to release. The inspection includes evaluation for visible particulate matter, foreign matter, discoloration, precipitation, cloudiness, leakage, container or closure defects, and other unexpected abnormalities. The CSP and its labeling are verified against the patient prescription/medication order, including drug, strength, volume, patient information, and applicable labeling requirements. Prior to dispensing, the pharmacist performs a final independent verification that includes a second visual inspection of the CSP, container-closure integrity, and labeling against the prescription.

Any CSP with an unacceptable appearance or other identified defect is rejected, segregated, and investigated in accordance with facility SOPs. Our quality assurance policy requires that any batch with 10% or greater visual inspection failures be immediately isolated and investigated to determine the cause and appropriate corrective action

14. How often do you perform glove fingertip and medial fill testing?

Every 3 months for compounders and yearly for RPh with direct oversight

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Our pharmacy maintains a comprehensive initial and ongoing training and competency program for all personnel performing sterile compounding. Initial training includes both didactic education and hands-on, one-on-one training.
Personnel complete the CriticalPoint (TRC) online sterile compounding course, which provides comprehensive training covering all aspects of sterile compounding. In addition, Pharmacy Stars (Compounding360) provides training in sterile and non-sterile compounding, hazardous drug handling and compounding, and other applicable topics, with quizzes to assess understanding. Pharmacy Stars also contains our pharmacy-specific SOPs, which trainees are required to read, review, and acknowledge as part of their training.
Following the didactic portion, each trainee receives individualized hands-on training using an internally developed training guide. Training covers activities both inside and outside the cleanroom, including garbing and aseptic technique, cleaning and disinfection, compounding procedures, vial washing and sterilization, QC procedures, autoclave processes, labeling and verification, documentation, and other applicable compounding-related tasks. Training consists of observation followed by directly supervised performance by the trainee.
The PIC or designated qualified individual verifies and signs off on completion of the required training and competencies. Once all required training and competencies are successfully completed, the trainee proceeds to the required GFT/Media Fill qualification before being authorized to perform sterile compounding independently.
Ongoing competency is maintained through periodic training and direct oversight, with compounders evaluated every three months and pharmacists annually. Additional training and competency assessment are provided whenever procedures or SOPs change or when retraining is otherwise indicated.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Our facility follows current USP <797> requirements for Category 3 compounding. Primary engineering controls (PECs) are cleaned and disinfected on each day of compounding using sterile TB1-3300 with a 1-minute dwell time, followed by sterile 70% IPA. Sterile 70% IPA is also used for routine and in-process disinfection of PEC work surfaces and prior to compounding. Peridox RTU is used as the facility's sporicidal disinfectant, with a 3-minute dwell time, at the USP <797> Category 3-required frequencies. The PEC interior, pass-through chamber, work surfaces outside the PEC, and floors receive sporicidal treatment at least weekly; removable PEC trays and the area beneath them receive sporicidal treatment monthly.

Secondary engineering controls and other classified-area surfaces, including walls, doors/frames, ceilings, shelving/bins, and applicable equipment, are cleaned and disinfected according to USP <797> Category 3 frequencies. Sterile 70% IPA is used for routine residue-free disinfection where applicable, while Peridox RTU is used for the required sporicidal treatment. All agents are used according to manufacturer-required dwell/contact times, and sterile cleaning and disinfecting agents are used within the PEC. Cleaning and disinfection activities are documented in accordance with facility SOPs.

17. Who performs the sterile compounding process at your facility?

Qualified sterile compounding technicians

18. Who is responsible and accountable for the sterile compounding process at your facility?

PIC or designated person

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

When compounded products are shipped or mailed, they are packaged in Kangaroo pouch cold-chain mailers using packaging configurations supported by validated shipping studies. The validated packaging system is used to maintain appropriate product temperature, protect the preparation from physical damage, and preserve product quality, safety, and efficacy throughout transit.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? BSC, CVE, LAFW		
2. Are you complying with all USP 800 guidelines?	✓Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	✓Yes	No
4. Is your BSC or CACI vented 100% to the outside?	✓Yes	No
5. Do you have a negative pressure buffer room at your facility?	✓ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	✓ Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	✓ Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	✓No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

Patients/consumers receiving hazardous drug products are provided with appropriate counseling regarding the proper handling, storage, and disposal of the medication and its container. Product labels include applicable storage requirements and hazardous drug warnings, and auxiliary labels are used to provide additional handling and safety information necessary for the proper use of the product. Counseling and labeling are provided to ensure patients and caregivers are aware of appropriate precautions when handling hazardous drug products and containers.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

The process for Hazardous sterile training remains essentially the same as mostly the same principles apply in the HD buffer room but there is an emphasis on HD specific training specifically related to garbing, product handling and hazardous drug list, spill management, HD waste, employee exposure, and specific aseptic techniques related to HD compouding.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

NAD+ Injection, Glutathione Injection, Sermorelin Injection, Semaglutide/Pyridoxine Injection, Tirzepatide/Pyridoxine Injection

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

Once every 3 months for compounding technicians and once yearly for pharmacists with direct oversight

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ✓ Yes No

4. What is the frequency for completing volumetric active air sampling?

Once monthly

5. What is the frequency for completing surface sampling? Once weekly including DCA of each Cat 3 compounded batch		
6. What is the frequency for using sporicidal agents? *Monthly for entire cleanroom including additional weekly application of PEC surfaces including equipment inside, worksurfaces outside of PEC, floors and pass through chambers*		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	✓ Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	✓ Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dino Dzanic

Name of Person who Completed the Form

Pharmacist-in-Charge

Title

Signature (copies or stamps not accepted)

8/14/26

Date

Board Use Only	Date Received:_____ Date Approved:_____ Approved By:_____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Meta Pharmacy Services

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 500 Pilot Road, Suite A

City: Las Vegas State: NV Zip: 89119

Mailing Address (if different from physical address): 500 Pilot Road, Suite A

City: Las Vegas State: NV Zip: 89119

Telephone: (702) 356-3597 Website: www.metapharmacyservices.com

Licensing Company Email: admin@metapharmacyservices.com

Section 2: Personal Information

First: Andrew Middle: M. Last: Vukadinovich

Alias(es, nicknames, name changes, etc.): N/A-Not Applicable

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Union University			From - To (MM/YY – MM/YY): 08/95-05/99
Address: 1050 Union University Drive	City: Jackson	State: TN	Zip: 38305
Diploma/Degree obtained, if any: BS, Psychology and BS, Business Administration			
School Name: John Overton High School			From - To (MM/YY – MM/YY): 08/91-5/95
Address: 4820 Franklin Rd,	City: Nashville,	State: TN	Zip: 37220
Diploma/Degree obtained, if any: Diploma			
School Name: N/A-Not Applicable			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/26-present	[redacted]	Las Vegas,	NV	[redacted]
04/25-04/26		Las Vegas,	NV	
09/19-04/25		North Port	FL	
02/16 -09/19		Ocala,	FL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Meta Pharmacy Services, LLC			04/25-present	
Business Address	**City**	**State**	**Zip**	
8352 West Warm Springs Road, Suite 120,	Las Vegas	NV	89113	
Phone	**Title**			
(702) 754-0172	Vice President and Secretary			
Description of Duties				
Manage pharmacy administration and operations. Implement corporate strategies, policies, and initiatives. Manage budgets, financial reporting, and forecasting to support corporate objectives				

Business Name			From - To (MM/YY – MM/YY)	
Belmar Pharma Solutions			07/21-04/25	
Business Address	**City**	**State**	**Zip**	
2500 Lakepointe Pkwy	Odessa	FL	33556	
Phone	**Title**			
(877) 418-4692	Director, Operations			
Description of Duties				
Oversaw day-to-day operational workflows, ensuring efficiency, safety, compliance and optimal patient care delivery				

Business Name			From - To (MM/YY – MM/YY)	
Columbia Care Florida LLC			03/18-09/20	
Business Address	**City**	**State**	**Zip**	
528 SW Highway 17	Arcadia,	FL,	34266	
Phone	**Title**			
	National Director, Manufacturing / Market Director, Florida			
Description of Duties				
Oversaw production operations, ensuring efficiency, quality, safety, and continuous improvement across manufacturing processes.				

Business Name			From - To (MM/YY – MM/YY)	
Wells Pharmacy Network			08/15-03/18	
Business Address	**City**	**State**	**Zip**	
1210 SW 33rd Ave,	Ocala,	FL	34474	
Phone	**Title**			
(800) 622-4510	Director, Pharmacy Operations			
Description of Duties				
Oversaw day-to-day operational workflows, ensuring efficiency, safety, compliance and optimal patient care delivery				

Business Name			From - To (MM/YY – MM/YY)	
N/A-Not Applicable				
Business Address	**City**	**State**	**Zip**	
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
N/A-Not Applicable				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew M. Vukadinovich
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8/17/2026
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Andrew M. Vukadinovich, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8/17/2026
Date

Subscribed and Sworn to before me this 17th day of August 2026.

Misty Richardson
Notary Public Signature

MISTY DAWN RICHARDSON
Notary Public, State of Nevada
Appointment No. 24-1238-01
My Appt. Expires Mar 14, 2028

(Seal)

9D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada	☐ New Pharmacy	■ Retail/Community	☐ Retail/Community
☐ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	■ Non-sterile Compounding
			■ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 02986		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Quality Compounding Rx of America

Physical Address: 801 S. Rancho Drive STE E7

City: Las Vegas State: NV Zip: 89106

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702.984.6640 Toll Free # (NAC 639.708, NRS 639.23286): 833.467.8575

Fax: 877-909-7750 Contact Email: licensing@qcrxusa.com

Website: https://www.qcrxusa.com

Nevada Business License # (if applicable) NV20253447879, NV20232669489

Supervising/Managing Pharmacist Name (NRS 639.220): Jubdatul Arefin

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 18911

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Jubdatul Arefin	NV Pharmacist Registration #: 18911
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A
Name: N/A	Credentials: N/A	%: N/A

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): _____

Corporation/Organization Name: Trinity Crest Holdings LLC

Mailing Address: 801 S. Rancho Drive STE E7

City: Las Vegas State: NV Zip: 89106

Telephone: 702.984.6640 Email: licensing@qcrxusa.com

Contact Person Name: Ruben Sukiasyan

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Manging Pharmacist (title) for Quality Compounding Rx of America (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Jubdatul Arefin

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

6/25/26

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Jubdatul Arefin Pharmacist Registration #: 18911

Pharmacy Name: Quality Compounding Rx of America

Initial each statement below to indicate you have read and agree with the following:

JA — I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

JA — I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

JA — I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

JA — I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

JA — I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board/Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted) — Date: 6/25/26

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ruben Sukiasyan

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

06/25/2026

Date

Board Use Only	Date Received: 7/2/26	Amount: $500 CK 109 ✓

Oregon
Tina Kotek, Governor

Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR, 97232
Phone: 971-673-0001
Fax: 971-673-0002
pharmacy.compliance@bop.oregon.gov
www.oregon.gov/pharmacy

November 15, 2024

Quality Compounding Rx Of America
Pharmacist-in-Charge
801 S Rancho Dr #E7
Las Vegas NV 89106

Re: Case No. 2024-0931

The Board of Pharmacy is investigating a complaint regarding Quality Compounding Rx Of America (Quality). The complaint is Quality dispensed and shipped prescription medication to a patient in Oregon without a drug outlet registration.

Please respond by submitting a typed and signed statement by **November 25, 2024**. The statement should indicate if the allegation is true or not. If the allegation is true, please indicate the date this began and provide a report with prescription number, patient name, drug name, address where shipped, and the date drug was shipped into Oregon. Please also describe the problem, explain in detail why it happened, and describe any steps taken to prevent this type of incident from reoccurring.

PLEASE NOTE: Responses are formal statements to the Board's inquiry into this investigation. The Board may use the information provided in the response statements to determine whether disciplinary action is warranted.

If you have any questions, please contact me at joseph.ball@bop.oregon.gov .

Sincerely,

Joseph S. Ball, R.Ph.
Chief Compliance Officer

Oregon
Tina Kotek, Governor

Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR, 97232
Phone: 971-673-0001
Fax: 971-673-0002
pharmacy.compliance@bop.oregon.gov
www.oregon.gov/pharmacy

March 12, 2025

Quality Compounding Rx of America
801 S Rancho Dr #E7
Las Vegas NV 89106

Re: Case No. 2024-0931

The Oregon Board of Pharmacy proposes to impose a civil penalty against Quality Compounding Rx of America (Respondent) for the reasons explained in the enclosed Notice of Proposed Civil Penalty (Notice).

The Respondent has the right to contest this action by having a formal hearing before an Administrative Law Judge. The Respondent must be represented by an attorney.

If the Respondent wants a hearing, its **written** request for a hearing must be filed by an attorney for the Respondent and must be received by the Board within twenty-one (21) days from the date the Notice is served.

If the Respondent does **not** want to contest the Board's proposed action, it may agree to it by having an authorized representative sign and return the enclosed Consent Order.

If the Respondent fails to request a hearing within 21 days, the Board will enter a Final Order by Default against the Respondent. The Final Order by Default will impose action as determined by the Board. Pursuant to OAR 137-003-0505 the Board designates its file as the evidentiary record in this proceeding for purposes of establishing a prima facie case in the event of a default.

If you have any questions, or if we can be of further assistance, please contact our office at pharmacy.compliance@bop.oregon.gov. Please provide your name, your preferred contact method and information, and case number as it appears above. Alternatively, you may contact our office at the address and phone number listed above.

Sincerely,

Compliance Department

Enclosures: Notice of Proposed Civil Penalty
Consent Order
Remittance Form

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of	)	Case No. 2024-0931
	)	
Quality Compounding Rx of America	)	NOTICE OF PROPOSED
	)	CIVIL PENALTY
Respondent	)	
	)	

Under the authority granted to the Oregon Board of Pharmacy (Board) pursuant to ORS Chapter 689 (the Oregon Pharmacy Act), including ORS 689.135, 689.145, 689.155 and 689.832(1), the Oregon Board of Pharmacy (Board) proposes to impose a civil penalty against Quality Compounding Rx Of America located at 801 S Rancho Dr #E7 in Las Vegas, NV (Respondent) because Respondent violated the Oregon Pharmacy Act and Board rules as set forth below:

Respondent is not registered with the Board as a drug outlet.

On or about 7/10/2024, Respondent shipped a prescription medication to a patient's home address in Oregon without a drug outlet registration with the Board in violation of OAR 855-041-1060(2), ORS 689.305, and ORS 689.335 which is grounds for imposition of a civil penalty pursuant to ORS 689.832(1), 689.335(1), 689.405(1)(e)(B), and 689.445.

Based on this alleged violation, the Board proposes to impose a civil penalty in an amount of $10,000.

HEARING RIGHTS

You are entitled to a hearing as provided by the Administrative Procedures Act (ORS Chapter 183). If you wish to have a hearing, you must file a written request for hearing with the Board within 21 days from the date this notice was mailed. You may send or deliver a request for hearing to:

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Fax (971) 673-0002

If a request for hearing is not received within this 21-day period, your right to a hearing shall be considered waived.

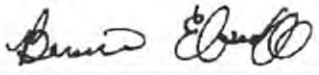
If you request a hearing, you will be notified of the time and place of the hearing. Before the commencement of the hearing, you will be given information on the procedures, right of representation and other rights of parties relating to the conduct of the hearing. You may be

represented by legal counsel and legal aid organizations may be able to assist you if you have limited financial resources. If you are a corporation, partnership, limited liability company, agency, trust, government body or an unincorporated association, you must be represented by an attorney licensed to practice in Oregon.[1]

If you do not request a hearing within 21 days, or if you withdraw a hearing request, notify the Board or Administrative Law Judge that you will not appear, or fail to appear at a scheduled hearing, the Board may issue a final order by default. If the Board issues a final order by default, it designates the relevant portions of its files on this matter, including all materials that you have submitted relating to this matter, as the record for the purpose of proving a prima facie case upon default. ORS 183.417(4).

NOTICE TO ACTIVE DUTY SERVICEMEMBERS: Active duty service members have a right to stay these proceedings under the federal Service members Civil Relief Act. For more information contact the Oregon State Bar at 800-452-8260, the Oregon Military Department at 503-584-3571 or the nearest United States Armed Forces Legal Assistance Office through http://legalassistance.law.af.mil. The Oregon Military Department does not have a toll-free phone number.

BOARD OF PHARMACY
FOR THE STATE OF OREGON



Brianne Efremoff, Pharm.D, R.Ph.,
Compliance Director

3/12/2025
Date

DATE OF MAILING 3/12/2025

[1] A request for hearing will not be deemed to be invalid solely because it was not signed by a person licensed to practice law in Oregon as long as an attorney ratifies the request, in writing, within 28 days of the date the request for a hearing was received by the agency.

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF OREGON

In the Matter of	)	Case No. 2024-0931
	)	
Quality Compounding Rx of America	)	CONSENT ORDER
	)	
Respondent	)	

WHEREAS, the Board of Pharmacy of the State of Oregon has filed a Notice of Proposed Civil Penalty ("Notice") regarding the Respondent in the above-captioned matter; and

WHEREAS, the above-noted Notice was duly served on the Respondent as required by law; and

WHEREAS, the parties are desirous of resolving and settling those matters contained in the above-noted Notice without further proceedings thereon; and

WHEREAS, the Respondent is aware of the right to a hearing with the assistance of counsel and the right to judicial review of the Board's decision, and hereby freely and voluntarily waives those rights; and

WHEREAS, the Respondent admits that the facts alleged in the above-noted Notice are true, that the Respondents conduct, as admitted, violated the statutes and rules cited in the Notice, and that legal cause exists pursuant to ORS 689.335, 689.405, and 689.445 for disciplinary action by the Board; and

WHEREAS, the Respondent consents to the disciplinary action as set forth herein;

The Board finds that the allegations in the Notice are true and hereby:

1. The Respondent shall pay a civil penalty to the Board in the amount of $10,000 with $9,000 stayed pending no further violation for three years. If respondent violates any term or condition of this Consent Order, within three (3) years of the effective date of this Consent Order, the Board may take action to lift the stayed portion of the civil penalty. Payment of the $1,000 portion of the civil penalty not stayed to be made within ten (10) days from the date this Consent Order becomes final.

2. This Consent Order shall become effective immediately upon issuance by the Board.

3. In the event that the Respondent fails to timely pay the civil penalty as ordered herein, the Board may take further action, after notice and hearing.

CONSENT

I hereby acknowledge that I am the authorized representative of respondent. On behalf of the respondent, I hereby acknowledge that I have read and understand the above-noted Notice and the terms of the Consent Order. I hereby acknowledge that I understand that the Consent Order with incorporated Notice is a public record and shall be available via the Board's online licensure verification; is available upon written request pursuant to public disclosure laws; and shall be reported to the National Practitioner Data Bank as required by federal law. I agree to the Board entering the Consent Order.

_____ _____

Authorized Representative Date
Quality Compounding Rx Of America
Respondent

IT IS SO ORDERED.

BOARD OF PHARMACY
FOR THE STATE OF OREGON

_____ _____

Brianne Efremoff, Pharm.D, R.Ph., Date
Compliance Director

CIVIL PENALTY **$ 1,000.00**

CASE # **2024-0931**

PAYER: Quality Compounding Rx of America
801 S Rancho Dr #E7
Las Vegas NV 89106

REMIT TO: OREGON BOARD OF PHARMACY
800 NE OREGON ST, SUITE 150
PORTLAND, OR 97232

Office use:	
Date	
Check/MO	
Receipt	
Entered by	
Allocated	

THIS FORM MUST ACCOMPANY PAYMENT TO ENSURE PROPER FILING

Oregon
Tina Kotek, Governor

Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR, 97232
Phone: 971-673-0001
Fax: 971-673-0002
pharmacy.compliance@bop.oregon.gov
www.oregon.gov/pharmacy

November 15, 2024

Quality Compounding Rx Of America
Pharmacist-in-Charge
801 S Rancho Dr #E7
Las Vegas NV 89106

Re: Case No. 2024-0931

The Board of Pharmacy is investigating a complaint regarding Quality Compounding Rx Of America (Quality). The complaint is Quality dispensed and shipped prescription medication to a patient in Oregon without a drug outlet registration.

Please respond by submitting a typed and signed statement by **November 25, 2024**. The statement should indicate if the allegation is true or not. If the allegation is true, please indicate the date this began and provide a report with prescription number, patient name, drug name, address where shipped, and the date drug was shipped into Oregon. Please also describe the problem, explain in detail why it happened, and describe any steps taken to prevent this type of incident from reoccurring.

PLEASE NOTE: Responses are formal statements to the Board's inquiry into this investigation. The Board may use the information provided in the response statements to determine whether disciplinary action is warranted.

If you have any questions, please contact me at joseph.ball@bop.oregon.gov .

Sincerely,

Joseph S. Ball, R.Ph.
Chief Compliance Officer

Quality Compounding Rx of America LLC (QCRX)

Officers & Directors

George Nordanyan – Principal & Founder

Sky Countryman – Co-Founder & CEO

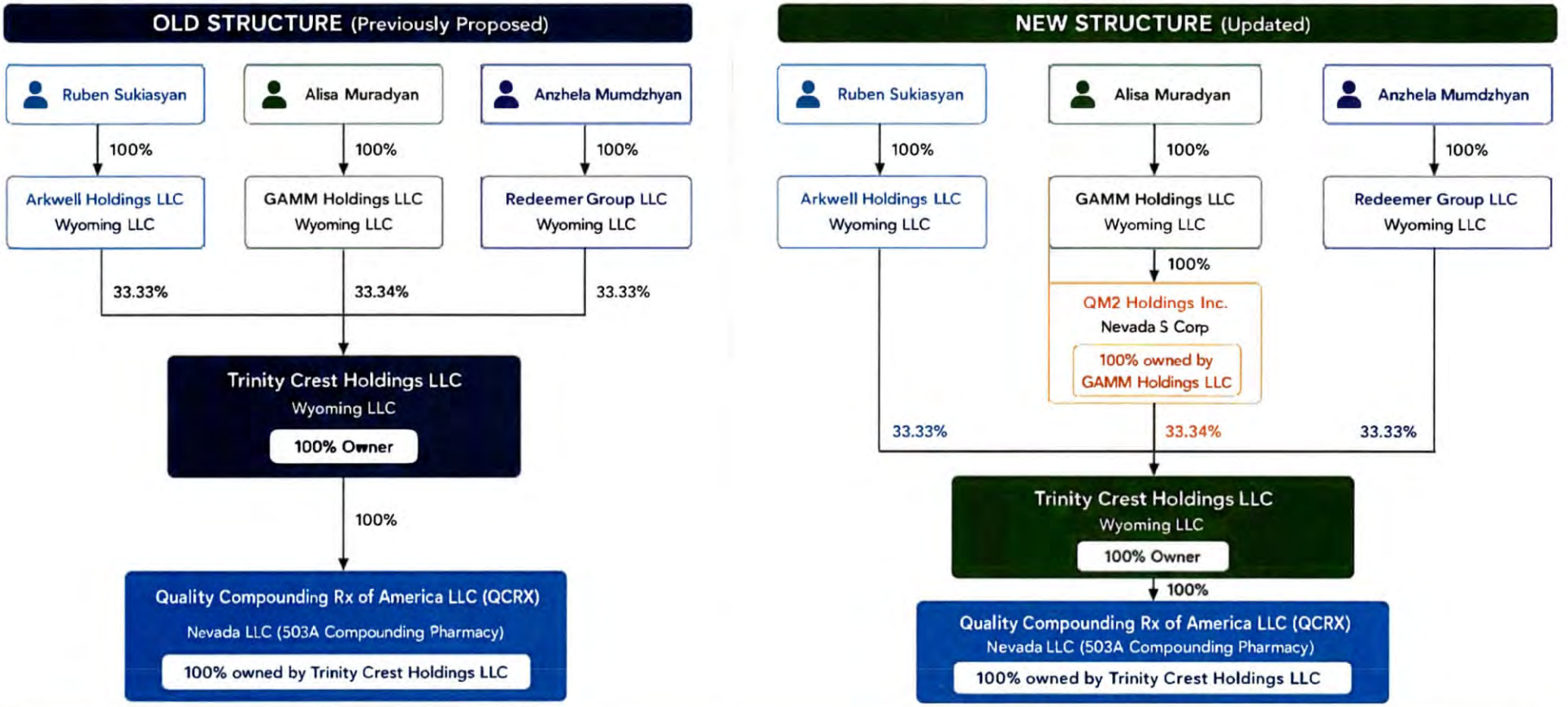
Tim Johnston – National Director of Business Development

QCRX Ownership Structure



QCRX RESTRUCTURE: OLD STRUCTURE vs. NEW STRUCTURE

KEY DIFFERENCE: Addition of QM2 Holdings Inc. (Nevada S Corp) – 100% owned by GAMM Holdings LLC – which holds 33.34% of Trinity Crest Holdings LLC.



SUMMARY

- In both structures, Trinity Crest Holdings LLC (Wyoming LLC) owns 100% of Quality Compounding Rx of America LLC (QCRX) (Nevada LLC).
- The only change in the new structure is the addition of QM2 Holdings Inc. (Nevada S Corp), which is 100% owned by GAMM Holdings LLC and holds a 33.34% ownership interest in Trinity Crest Holdings LLC.

OWNERSHIP OF TRINITY CREST HOLDINGS LLC (NEW STRUCTURE)

Arkwell Holdings LLC (Wyoming LLC)	QM2 Holdings Inc. (Nevada S Corp)	Redeemer Group LLC (Wyoming LLC)
33.33%	33.34%	33.33%

LEGEND: Operating Company · Parent / Holding Company · Intermediate Entity (New) · Arkwell Ownership · GAMM Ownership · Redeemer Ownership

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Quality Compounding Rx of America Holding, LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 10/01/2025, and in good standing in this State.

I further certify that the above DOMESTIC LIMITED-LIABILITY COMPANY (86) has its formation or qualification document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 06/16/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202606166753739

You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Quality Compounding Rx of America

Pharmacy/Wholesaler License # (if applicable): PH02986

Physical Address: 801 S. Rancho Drive STE E7

City: Las Vegas State: NV Zip: 89106

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 702.984.6640 Website: https://www.qcrxusa.com

Licensing Company Email: licensing@qcrxusa.cm

Section 2: Personal Information

First: Jubdatul Middle: Last: Arefin

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Massachusett's College of Pharmacy and Health Sciences			09/2007- 05-2013	
Address		City	State	Zip
179 Longwood Ave		Boston	MA	02115
Diploma/Degree obtained, if any				
PharmD				
School Name			From - To (MM/YY – MM/YY)	
Benjamin N Cardozo High School			09/2003-06/2007	
Address		City	State	Zip
57-00 223rd St		Bayside	NY	11364
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]	City	State	[redacted]
08/2019- Current		Las Vegas	NV	
From - To (MM/YY – MM/YY)	[redacted]	City	State	[redacted]
01/2015-08/2015		Las Vegsa	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Quality Compounding Rx of America LLC			03/2026- Current	
Business Address		**City**	**State**	**Zip**
801 S Rancho Drive Suite E7		Las Vegas	NV	89106
Phone	**Title**		**Number of Employed Hours**	
702-984-6640	Pharmacist in Charge		480	
Description of Duties				
Pharmacist in Charge managing a Sterile and Non-sterile compounding Pharmacy				

Business Name			From - To (MM/YY – MM/YY)	
Summerlin Hospital			03/2025-11/2025	
Business Address		**City**	**State**	**Zip**
657 N Town Center Dr		Las vegas	NV	89144
Phone	**Title**		**Number of Employed Hours**	
7022337000	Assistant Director of Pharmacy		1,280	
Description of Duties				
Pharmacy P&T committee member, Formulary Management, over see daily pharmacy operations, Over see daily sterile operations				

Business Name			From - To (MM/YY – MM/YY)	
Quality Compounding Rx of America LLC			06/2023- 03/2025	
Business Address		**City**	**State**	**Zip**
801 S Rancho Dr suite E7		Las Vegas	NV	89106
Phone	**Title**		**Number of Employed Hours**	
7029846640	Pharmacist in Charge		3,760	
Description of Duties				
Pharmacist in Charge managing a Sterile and Non-sterile compounding Pharmacy				

Business Name			From - To (MM/YY – MM/YY)	
Walmart Pharmacy #5258			04/2019- 06/2023	
Business Address		**City**	**State**	**Zip**
5850 W Craig Rd		Las vegas	NV	89130
Phone	**Title**		**Number of Employed Hours**	
7023951240	Pharmacist in Charge		8,320	
Description of Duties				
Pharmacist in Charge for Retail Chain Pharmacy				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

6/25/26
Date

I, Jubdatul Arefin, **certify that as the designated representative for**

Quality Compounding Rx of America,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JA I am at least 21 years of age;
3. JA I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JA I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JA I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JA I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JA I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jubdatul Arefin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/25/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jubdatul Arefin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/25/26

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark County

I, Jubdatul Arefin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

6/25/26

Date

State of Nevada
Clark County
Subscribed and Sworn to before me this 25 day of June, 2026 by Jubdatul Arefin

Notary Public Signature

K. BAYARD
Notary Public, State of Nevada
Appointment No. 16-2097-1
My Appt. Expires Apr 15, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Quality Compounding Rx of America

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 801 S. Rancho Drive STE E7

City: Las Vegas State: NV Zip: 89106

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702.984.6640 Toll Free # (NAC 639.708, NRS 639.23286): 833.467.8575

Fax: 877-909-7750 Contact Email: licensing@qcrxusa.com

Website: https://www.qcrxusa.com/

Nevada Business License # (if applicable) NV20253447879, NV20232669489

Supervising/Managing Pharmacist Name (NRS 639.220): Jubdatul Arefin

Supervising/Managing Pharmacist NV Pharmacist Registration #: 18911

Name of Designated Person(s) as defined by revised USP-797 guidelines: Nicole Sy

Email of Designated Person(s): nicolesy@qcrxusa.com

Telephone of Designated Person(s): 702.984.6640

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

■ Category 1 ■ Category 2 ☐ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ■ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 05/27/2026

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Once a week

10. Will you be performing sterile hazardous drug compounding? ■ Yes No

If you marked **"Yes"**, you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Glutathione
Bremelanotide
Methionine/Inositol/Choline
Methionine/Inositol/Choline/Methylcobalamin
Methionine/Inositol/Choline/Dexpanthenol/L-Carnitine/Thiamine
Ascorbic Acid
Methylcobalamin
Myers
NAD+
Semaglutide/Glycine
Semaglutide/Methylcobalamin
Semaglutide/NAD+
Testosterone Cypionate
Testosterone Enanthate
Tirzepatide/Glycine
Tirzepatide/Methylcobalamin
Tirzepatide/NAD+
VitaminB Complex

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL Bio Pharma

Address: 840 Research Parkway, Suite 546

City: Oklahoma City State: OK Zip: 73104

Telephone: 800.393.1595

13. What is your procedure for visual inspection of compounded sterile products?

All sterile finished products are visually inspected for Container Closure (leakage, cracks, improper seals), particles, foreign matter, and other visible defects prior to labeling

14. How often do you perform glove fingertip and medial fill testing?

Every Six (6) months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Initial and ongoing
Critical Point
Competencies- Equipment, Aseptic Technique, Garbing, Cleaning and Disinfection, Achieving and/or maintaining sterility, Documentation, PECs (HEPA), Transferring items into controlled environment, Movement, Hand hygiene

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

PECs- Cleaned with Peridox followed by sIPA 70%
SEC - Cleans floors and high touch point area with TB1-3300 Daily, Walls, Ceilings, Floor - monthly with Sporicidal (peridoxRTU), Floors also with Periodox with high traffic
sIPA 70%
TB1-3300
Peridox

17. Who performs the sterile compounding process at your facility?

Arjay Fernando, Russ Fernando, Josh Fernando, Adrian Samson (Pharmacy Technicians)

18. Who is responsible and accountable for the sterile compounding process at your facility?

Arjay Fernando
Nicole Sy

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Products are shipped with insulated packaging and refrigerant packs to maintain the required temperature range of 2–8° throughout transit

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? NuAire BSC Type II		
2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	■ No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	■ No
9. If yes, list the name of the device: N/A		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

Patients receive guidance in a Patient Information Sheet that covers four key areas:

1. Safe Handling – Instructions on PPE use (gloves, hand washing), restrictions on who may handle the medication, and what to do in the event of accidental skin contact.

2. Storage – Direction to follow label instructions, store in original packaging, and keep medications away from children and pets.

3. Disposal – Step-by-step instructions for disposing of sharps, empty vials/containers with residue, and contaminated materials (gloves, gauze, wipes) as hazardous waste.

4. Disposal Resources & Emergency Contacts – Patients are directed to drug take-back programs, DEA take-back events, mail-back programs, and local hazardous waste collection sites, as well as Poison Control (1-800-222-1222) and 911 for emergencies.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Initial and ongoing
Critical Point - hazardous drugs
Competencies- Equipment, Aseptic Technique, Garbing, Cleaning and Disinfection, Achieving and/or maintaining sterility, Documentation, BSCs (HEPA), Transferring items into controlled environment, Movement, Hand hygiene
Review and Overview of Hazardous Drugs to be Compounded
PPE
Spill Management
Disposal
Communication and response to potential or known exposure

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

N/A

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

N/A

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? N/A Yes No

4. What is the frequency for completing volumetric active air sampling?

N/A

5. What is the frequency for completing surface sampling? N/A			
6. What is the frequency for using sporicidal agents? N/A			
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	N/A	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	N/A	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nicole Sy

Name of Person who Completed the Form

Designated Person

Title

Signature (copies or stamps not accepted)

06/29/26

Date

Board Use Only	Date Received: 7/2/26 Date Approved: _____ Approved By: _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Quality Compounding Rx of America, LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 801 S. Rancho Dr Suite E7

City Las Vegas State Nv Zip 89106

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-984-6640 Website www.qcrxusa.com

Licensing Company Email _____

Section 2: Personal Information

First Alisa Middle _____ Last Muradyan

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City Burbank [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Harvard Medical School, Harvard University		6/2018 – 06/2018	
Address: 25 Shattuck St	City: Boston	State: MA	Zip: 02115
Diploma/Degree obtained, if any: Post-Doctoral CE on Bleckburn Obesity Courses. Certificate Obtained			

School Name		From - To (MM/YY – MM/YY)	
University of Southern California, School of Pharmacy		08/2002 – 05/2006	
Address: 1985 Zonal Ave.	City: Los Angeles	State: CA	Zip: 90033
Diploma/Degree obtained, if any: Doctor of Pharmacy PharmD			

School Name		From - To (MM/YY – MM/YY)	
California State University, Northridge		8/1996 – 5/2001	
Address: 18111 Nordhoff st	City: Northridge	State: CA	Zip: 91330
Diploma/Degree obtained, if any: Bachelors of Arts in Biology. BA.			

School Name		From - To (MM/YY – MM/YY)	
Glendale Community College		8/1995 – 5/2001	
Address: 1500 N. Verdugo Road	City: Glendale	State: CA	Zip: 91208
Diploma/Degree obtained, if any: classes. over summer breaks. P.E. classes.			

School Name		From - To (MM/YY – MM/YY)	
Glendale High School		9/1993 – 6/1996	
Address: 1440 E. Broadway st.	City: Glendale	State: CA	Zip: 91207
Diploma/Degree obtained, if any: High School Diploma			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2/2011 – Current	[redacted]	Burbank	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Well Care Pharmacy			From - To (MM/YY – MM/YY): 02/2024 – Current
Business Address: 1108 ½ W. Glenoaks Blvd	City: Glendale	State: CA	Zip: 91201
Phone: (818) 551-0102	Title: Pharmacist in Charge.		
Description of Duties: Duties of a pharmacist in Charge.			

Business Name: Cure Rx Compounding Pharmacy			From - To (MM/YY – MM/YY): 2/2011 – 7/2014
Business Address: Sunset Ave.	City: Los Angeles.	State: CA	Zip: 90021
Phone: (323) 667-1111	Title: Pharmacist in Charge / Clinical Pharmacist		
Description of Duties: all the duties that are in the job description of a Pharmacist in Charge and overseeing the clinical and compounding operations			

Business Name: Priority Care Pharmacy.			From - To (MM/YY – MM/YY): 8/2013 – 8/2016
Business Address: 5652 Vineland Ave	City: North Hollywood	State: CA	Zip: 91601
Phone: (818) 508-8865	Title: Owner / Pharmacist in Charge		
Description of Duties: Lead the pharmacy team to operate efficient and safe drug dispensed at optimal patient care.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Alexa Mazadyan

Original Signature (electronic, copies or stamps not accepted)

6/22/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alisa, Muradyan

Print Name (First, Last)

Alisa Muradyan

Original Signature (electronic, copies or stamps not accepted)

6/22/2026

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

_____ _____

Original Signature **Date**

See Attached Notary Public Certificate

Subscribed and Sworn to before me this _____ day of _____.

See Attached Notary Public Certificate

_____

Notary Public Signature

See Attached Notary Public Certificate

(Seal)

CALIFORNIA ALL-PURPOSE ACKNOWLEDGEMENT

A Notary Public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles }

On June 22, 2026, before me, Lusine Babakhanyan, Notary Public,
personally appeared Alisa Muradyan

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of State of California that the foregoing paragraph is true and correct.

LUSINE BABAKHANYAN
COMM. #2533257
Notary Public - California
Los Angeles County
My Comm. Expires Oct. 21, 2029

WITNESS my hand and official seal.

SIGNATURE

PLACE NOTARY SEAL ABOVE

Though the information below is not required by law, it may prove valuable to persons relying on the document and could prevent fraudulent removal and reattachment of this form to another document.

Description of attached document

Title or type of document: Nevada state Board of Pharmacy

Document Date: 06/22/2026 Number of Pages: 7

Signer(s) Other than Named Above:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Quality Compounding Rx of America, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 801 S. Rancho Dr. Suite E7

City: Las Vegas State: NV Zip: 89106

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 702-984-6640 Website: https://www.qcrxusa.com

Licensing Company Email:

Section 2: Personal Information

First: Ruben Middle: Last: Sukiasyan

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Valley Village State: CA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Platt College			
Address	City	State	Zip
1000 S Fremont Ave Ste A9W	Alhambra	CA	91803
Diploma/Degree obtained, if any			
Associate Degree			

School Name		From - To (MM/YY – MM/YY)	
John Marshall HS			
Address	City	State	Zip
3939 Tracey St	Los Angeles	CA	90027
Diploma/Degree obtained, if any			
GED			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/18 to present	[redacted]	Studio City	CA	[redacted]
02/16 to 04/18		Glendale	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Quality Compounding Rx of America			03/26 to present	
Business Address		**City**	**State**	**Zip**
801 S. Rancho Dr. Suite E7		Las Vegas	NV	89106
Phone	**Title**			
702*984-6640	Director			

Description of Duties

Overseeing operations, strategic planning, performance metrics, and compliance. Collaborated with leadership to improve processes, achieve objectives, and support sustainable organizational growth.

Business Name			From - To (MM/YY – MM/YY)	
Accolade Recovery, Inc.			01/23 - 03/26	
Business Address		**City**	**State**	**Zip**
22209 Dolorosa St		Woodland Hills	CA	91367
Phone	**Title**			
818-660-2475	CEO			

Description of Duties

Led organizational strategy, operations, financial performance, compliance, and growth initiatives. Directed teams, managed budgets, improved efficiencies, and drove business development and organizational success.

Business Name			From - To (MM/YY – MM/YY)	
HonorView Hospice			11/23 to present	
Business Address		**City**	**State**	**Zip**
659 N. Escondido Blvd.		Escondido	CA	92025
Phone	**Title**			
619-798-8685	Board Member			

Description of Duties

Provide governance, strategic oversight, and fiduciary leadership. Reviewed financial performance, risk management, compliance, and long-term initiatives to support organizational stability and growth.

Business Name			From - To (MM/YY – MM/YY)	
Vital HC, Inc.			07/21 - present	
Business Address		**City**	**State**	**Zip**
4447 E. Broadway Rd. Suite 101		Mesa	AZ	85206
Phone	**Title**			
480-716-8007	Board Member			

Description of Duties

Provide governance, strategic oversight, and fiduciary leadership. Reviewed financial performance, risk management, compliance, and long-term initiatives to support organizational stability and growth.

Business Name			From - To (MM/YY – MM/YY)	
Lennox CMHC, Inc.			01/21 - 11/23	
Business Address		**City**	**State**	**Zip**
6843 Lennox Ave.		Van Nuys	CA	91405
Phone	**Title**			
818-839-4380	CEO			

Description of Duties

Led organizational strategy, operations, financial performance, compliance, and growth initiatives. Directed teams, managed budgets, improved efficiencies, and drove business development and organizational success.

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
AHPC Orange County, Inc.			06/19 to 10/25
Business Address	**City**	**State**	**Zip**
5000 Birch St. West Tower Suite 3000	Newport Beach	CA	92660
Phone	**Title**		
714-584-5805	Board Member		
Description of Duties			
Provided governance, strategic oversight, and fiduciary leadership. Reviewed financial performance, risk management, compliance, and long-term initiatives to support organizational stability and growth.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

_____
Print Name (First, Last)

_____ _____
Original Signature (electronic, copies or stamps not accepted) Date

---

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Ruben Sukiasyan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

_____ 6/22/2026
Original Signature **Date**

Subscribed and Sworn to before me this 22nd day of June, 2026

N.I. Sonnadara
_____
Notary Public Signature

NIPUNA ISHARA SONNADARA
Notary Public - California
Los Angeles County
Commission # 2421153
My Comm. Expires Oct 14, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Quality Compounding Rx America, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 801 S. Rancho Dr. Suite E7

City Las Vegas State NV Zip 89106

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-984-6640 Website www.qcrxusa.com

Licensing Company Email _____

Section 2: Personal Information

First Anzhela Middle _____ Last Mumdzhyan

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Sun Valley State CA Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Devry University		2011 2013	
Address	City	State	Zip
	Los Angeles	CA	
Diploma/Degree obtained, if any			
Human Resource Management			

School Name		From - To (MM/YY – MM/YY)	
Grant High School		1999 - 2002	
Address	City	State	Zip
	North Hollywood	CA	
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2007 2026	[redacted]	Sun Valley	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or in a related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Dordulian Law Group			03/26 to present	
Business Address		**City**	**State**	**Zip**
550 North Brand Blvd Suite 1990		Glendale	CA	91203
Phone	**Title**			
818.322.4056	HR/Manager			

Description of Duties

Manage employee onboarding, employee records, payroll, benefits, staff supervision, office operation, policy compliance, and employee relations. Coordinate daily administrative functions and support overall business operations.

Business Name			From - To (MM/YY – MM/YY)	
ExpertMRI			03/2018 - 12/2021	
Business Address		**City**	**State**	**Zip**
9500 Artesia Blvd		Bellflower	CA	90706
Phone	**Title**			
562.222.0468	Client Relations			

Description of Duties

Maintained positive client relationships by serving as the primary point of contact, responding to inquiries, resolving concerns, coordinating services, tracking client needs, and ensuring customer satisfaction.

Business Name			From - To (MM/YY – MM/YY)	
Global Holdings			1/2006 to 2/2017	
Business Address		**City**	**State**	**Zip**
550 North Brand Blvd Suite 2000		Glendale	CA	91203
Phone	**Title**			
	HR/Manager			

Description of Duties

Managed hiring, on-boarding, employee records, payroll, benefits, staff supervision, office operation, policy compliance, and employee relations. Coordinate daily administrative functions and supported overall business operations.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Anzhela Mumdzhyan
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

6/22/26
Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

See attached acknowledgment

Notary Public Signature

(Seal)

CALIFORNIA ACKNOWLEDGMENT **CIVIL CODE § 1189**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles }

On June 22, 2026 (*Date*) before me, Delia Horta "Notary Public" (*Here Insert Name and Title of the Officer*),

personally appeared Anzhela Numdzhyan (*Name(s) of Signer(s)*)

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

DELIA HORTA
Notary Public - California
Los Angeles County
Commission # 2463386
My Comm. Expires Oct 13, 2027

Place Notary Seal and/or Stamp Above

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Signature Delia Horta
Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Nevada State Board of Pharmacy

Document Date: _____ Number of Pages: 7

Signer(s) Other Than Named Above: _____

Capacity(ies) Claimed by Signer(s)

Signer's Name: _____	Signer's Name: _____
☐ Corporate Officer – Title(s): _____	☐ Corporate Officer – Title(s): _____
☐ Partner – ☐ Limited ☐ General	☐ Partner – ☐ Limited ☐ General
☐ Individual ☐ Attorney in Fact	☐ Individual ☐ Attorney in Fact
☐ Trustee ☐ Guardian or Conservator	☐ Trustee ☐ Guardian or Conservator
☐ Other: _____	☐ Other: _____
Signer is Representing: _____	Signer is Representing: _____

©2019 National Notary Association

9E

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☒ Nevada ☐ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH n/a	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☐ Controlled substances DEA #: n/a ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☐ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☐ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Silver State Rx LLC

Physical Address: 3100 E Lake Mead Blvd, #9

City: North Las Vegas State: NV Zip: 89030

Mailing Address (if different from physical address): Same

City: Same State: Same Zip: Same

Telephone: 775-519-0500 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: pending Contact Email: [redacted]@gmail.com

Website: pending

Nevada Business License # (if applicable) NV20263641577

Supervising/Managing Pharmacist Name (NRS 639.220): Vinodkumar Gadley

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 09951

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Vinodkumar Gadley	NV Pharmacist Registration #: 09951
Name: n/a	NV Pharmacist Registration #: n/a
Name: n/a	NV Pharmacist Registration #: n/a
Name: n/a	NV Pharmacist Registration #: n/a
Name: n/a	NV Pharmacist Registration #: n/a
Name: n/a	NV Pharmacist Registration #: n/a
Name: n/a	NV Pharmacist Registration #: n/a
Name: n/a	NV Pharmacist Registration #: n/a
Name: n/a	NV Pharmacist Registration #: n/a
Name: n/a	NV Pharmacist Registration #: n/a

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: n/a	Credentials: n/a	%: n/a
Name: n/a	Credentials: n/a	%: n/a
Name: n/a	Credentials: n/a	%: n/a
Name: n/a	Credentials: n/a	%: n/a
Name: n/a	Credentials: n/a	%: n/a

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: n/a

Parent Company (if any): n/a

Corporation Name: n/a

Mailing Address: n/a

City: n/a State: n/a Zip: n/a

Telephone: n/a Email: n/a

Contact Person Name: n/a

Date of SEC Registration: n/a | SEC Registration Number: n/a | Stock Exchange Symbol: n/a

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): None

Corporation/Organization Name: Silver State Rx LLC

Mailing Address: 3100 E Lake Mead Blvd, #9

City: North Las Vegas State: NV Zip: 89030

Telephone: 775-519-0500 Email: [redacted]@gmail.com

Contact Person Name: Geeta Sweeney

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: n/a

Mailing Address: n/a

City: n/a State: n/a Zip: n/a

Telephone: n/a Email: n/a

Contact Person Name: n/a

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: n/a

Business Name: n/a

Business Address: n/a

City: n/a State: n/a Zip: n/a

Telephone: n/a Email: n/a

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Managing Member (title) for Silver State Rx LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Geeta Sweeney

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

August 25, 2026

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Geeta Sweeney hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Managing Member (title) for Silver State Rx LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 25 day of August, 2026

Notary Public

DAVID SEKIGUCHI
Comm. # 2502615
Los Angeles County
California - Notary Public
Comm. Expires Oct. 21, 2028

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Vinodkumar Gadley Pharmacist Registration #: 09951

Pharmacy Name: Silver State Rx LLC

Initial each statement below to indicate you have read and agree with the following:

VG I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

VG I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

VG I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

VG I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

VG I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vinodkumar D. Gadley — 8/25/2026

Original signature of Managing Pharmacist (copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Geeta Sweeney

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

August 25, 2026

Date

Board Use Only	Date Received: 8/26/26	Amount: $300.00

Silver State Rx LLC

Officers and Members List
Attachment to Nevada State Board of Pharmacy — Pharmacy Application (Section 12, NRS 639.231(2)(b), NAC 639.214(5)(a))

Entity: Silver State Rx LLC — Nevada single-member limited liability company (non-publicly traded)
Pharmacy location: 3100 E Lake Mead Blvd, #9, North Las Vegas, NV 89030

Name: Geeta Sweeney
Title / Role: Managing Member (sole member)
Ownership %: 100%
Address: [redacted] Porter Ranch, CA [redacted]
Phone: [redacted]
Email: [redacted]

Notes

- The LLC has no other officers, directors, managers, or members.
- Ms. Sweeney is not a health professional and holds no pharmacist or practitioner license (NRS 639.232).
- The Managing Pharmacist / Designated Representative, Vinod Kumar Gadley (NV Pharmacist Registration #09951), is an employee and holds no ownership interest in the LLC.

Silver State Rx LLC

Ownership List — Top Four Members and All Members Holding 10% or More
Attachment to Nevada State Board of Pharmacy — Pharmacy Application (Section 12, NRS 639.231(3), NAC 639.214(4)(b))

Entity: Silver State Rx LLC — Nevada single-member limited liability company (non-publicly traded)
Pharmacy location: 3100 E Lake Mead Blvd, #9, North Las Vegas, NV 89030

#: 1
Name: Geeta Sweeney
Ownership %: 100%
Address: [redacted] Porter Ranch, CA [redacted]
Phone: [redacted]
Email: [redacted]

Notes

- Ms. Sweeney is the sole member; there are no other members, stockholders, or shareholders, and no other person holds a 10% or greater interest.
- Total ownership listed: 100%.

SECRETARY OF STATE

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Silver State RX LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 08/24/2026, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 08/24/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202608246911881
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Silver State Rx LLC

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 3100 E Lake Mead Blvd, #9

City: North Las Vegas State: NV Zip: 89030

Mailing Address (if different from physical address): Same

City: Same State: Same Zip: Same

Telephone: 775-519-0500 Website:

Licensing Company Email: [redacted]@gmail.com

Section 2: Personal Information

First: Vinodkumar Middle: Last: Gadley

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The Bombay School of Pharmacy		06/1970 to 06/1975	
Address	City	State	Zip
	Mumbai, India		
Diploma/Degree obtained, if any			
Bachelor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Elphisten College		06/1968 to 06/1970	
Address	City	State	Zip
	Mumbai, India		
Diploma/Degree obtained, if any			
Undergraduate Degree			

School Name		From - To (MM/YY – MM/YY)	
Premier High School		06/1967 to 06/1968	
Address	City	State	Zip
	Mumbai, India		
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2019 to Current	[redacted]	Las Vegas	NV	[redacted]
01/2016 to 12/2019		Las Vegas	NV	
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				
N/A				

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Health Works Pharmacy			03/2026 to Current	
Business Address		**City**	**State**	**Zip**
1703 Civic Center Dr. #5B		North Las Vegas	NV	89030
Phone	**Title**		**Number of Employed Hours**	
725-502-2208	Pharmacist in Charge		960	
Description of Duties				
Dispensing prescription drugs, inventory control, compliance with state and federal pharmacy laws, recordkeeping, supervision of pharmacy staff.				

Business Name			From - To (MM/YY – MM/YY)	
Goodwill Pharmacy			11/2025 to 02/2026	
Business Address		**City**	**State**	**Zip**
2610 S. Jones Blvd. #3		Las Vegas	NV	89146
Phone	**Title**		**Number of Employed Hours**	
702-213-3102	Pharmacist in Charge		640	
Description of Duties				
Dispensing prescription drugs, inventory control, compliance with state and federal pharmacy laws, recordkeeping, supervision of pharmacy staff.				

Business Name			From - To (MM/YY – MM/YY)	
Empire Pharmacy Consultants			01/2017 to 06/2025	
Business Address		**City**	**State**	**Zip**
936 SW 1st Ave			FL	33130
Phone	**Title**		**Number of Employed Hours**	
855-374-1029	Pharmacist		10,000	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Vinodkumar P. Jaddy

Original Signature (electronic, copies or stamps not accepted)

8/25/2026

Date

I, Vinodkumar Gadley, **certify that as the designated representative for**

Silver State Rx LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. h I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Vinodkumar Gadley
Print Name (First, Last)

Vinodkumar N. Gadley
Original Signature (electronic, copies or stamps not accepted)

8/25/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vinodkumar Gadley

Print Name (First, Last)

Vinodkumar N. Gadley — 8/25/2026

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, VINODKUMAR N. GADLEY, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Vinodkumar N. Gadley — 8/25/2026

Original Signature — **Date**

Subscribed and Sworn to before me this 25th day of August 2026.

M CARMEN TREVINO
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 15-3033-1
MY APPT. EXPIRES SEPTEMBER 11, 2027

Notary Public Signature

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Silver State Rx LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 3100 E Lake Mead Blvd, #9

City: North Las Vegas State: NV Zip: 89030

Mailing Address (if different from physical address): Same

City: Same State: Same Zip: Same

Telephone: 775-519-0500 Website:

Licensing Company Email: [redacted]@gmail.com

Section 2: Personal Information

First: Geeta Middle: Last: Sweeney

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Porter Ranch State: CA Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Moorpark College			09/1995 - 06/1997
Address	**City**	**State**	**Zip**
7075 Campus Rd	Moorpark	CA	93021
Diploma/Degree obtained, if any			
None			

School Name			From - To (MM/YY – MM/YY)
Granada Hills High School			09/1992 - 06/1995
Address	**City**	**State**	**Zip**
10535 Zelzah Ave	Granada Hills	CA	91344
Diploma/Degree obtained, if any			
High School Diploma (graduated 1995)			

School Name			From - To (MM/YY – MM/YY)
n/a			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
n/a			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
n/a			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2019 - Current	[redacted]	Porter Ranch	CA	[redacted]
02/2017 - 05/2019		Meridian	ID	
08/1996 - 02/2017		Granada Hills	CA	
n/a	Address	City	State	Zip
n/a	Address	City	State	Zip
n/a	Address	City	State	Zip
n/a	Address	City	State	Zip
n/a	Address	City	State	Zip
n/a	Address	City	State	Zip
n/a	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
AP Consulting			01/2020 - Current	
Business Address		**City**	**State**	**Zip**
Suraksha Vihar, Vikash Nagar Extension, Uttam Nagar		Delhi	India	110059
Phone	**Title**			
+91-995-371-7918	Consultant			
Description of Duties				
Consulting for medical, pharmaceutical, and cosmetics companies				

Business Name			From - To (MM/YY – MM/YY)	
RG Global Trading			04/2014 - 02/2021	
Business Address		**City**	**State**	**Zip**
860 S Los Angeles St		Los Angeles	CA	90014
Phone	**Title**			
n/a	Sourcing & Imports			
Description of Duties				
Sourced packaging from international suppliers (primarily Korea and China) for import into the United States				

Business Name			From - To (MM/YY – MM/YY)	
n/a				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
n/a				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
n/a				
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
n/a				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
n/a				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
n/a				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
n/a				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
n/a				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # n/a **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
n/a				
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

n/a

Original Signature (electronic, copies or stamps not accepted)

August 25, 2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Geeta Sweeney

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

August 25, 2026

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Geeta Sweeney, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

August 25, 2026

Date

Subscribed and Sworn to before me this 25 day of August.

Notary Public Signature

DAVID SEKIGUCHI
Comm. # 2502615
Los Angeles County
California - Notary Public
Comm. Expires Oct. 21, 2028
NXC1

(Seal)

9F

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
■ Nevada	☐ New Pharmacy	■ Retail/Community	☐ Retail/Community
☐ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: [redacted]
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 04768		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	■ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: VALLEY SPECIALTY PHARMACY

Physical Address: 3900 W CHARLESTON BLVD STE 130

City: LAS VEGAS State: NV Zip: 89102

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-359-0985 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 702-744-9212 Contact Email: INFO.VALLEYRX@GMAIL.COM

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): JAMES BELVIN

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 09659

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: JAMES BELVIN	NV Pharmacist Registration #: 09659
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☒ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NEVADA

Parent Company (if any): _____

Corporation/Organization Name: UNION HEALTH INC

Mailing Address: 3900 W CHARLESTON BLVD STE 3

City: LAS VEGAS State: NV Zip: 89102

Telephone: 702-359-0985 Email: INFO.VALLEYRX@GMAIL.COM

Contact Person Name: Leydi Diaz Echevarria

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the president (title) for Valley Specialty Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Leydi Diaz Echevarria

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

08/27/2026

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Leydi Diaz Echevarria hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the president (title) for Valley Specialty Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Leydi Diaz
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 27th day of August, 20 26

Jennifer Champeau
Notary Public

JENNIFER CHAMPEAU
Notary Public, State of Nevada
No. 12-8626-1
My Appt. Exp. Oct. 27, 2028

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: James Belvin Pharmacist Registration #: 09859

Pharmacy Name: _____

Initial each statement below to indicate you have read and agree with the following:

JB I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

JB I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

JB I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

JB I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

JB I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in <u>any</u> state?		✓

If you marked YES to any questions above, include the following information and provide a <u>signed statement of explanation</u>. <u>Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.</u>

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

_____ Sep 16, 2026

Original signature of Managing Pharmacist (copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Leydi Diaz Echevarria

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

08/27/2026

Date

Board Use Only	Date Received: 8/31/26	Amount: $500 cc

LIST OF OFFICERS AND DIRECTOR

Leydi Diaz Echevarria will be the President and the only Officer and 100% Owner of Union Health Inc dba VALLEY SPECIALTY PHARMACY.

Date: 08/27/21

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

UNION HEALTH INC

Nevada Business Identification # NV20232703156
Expiration Date: 02/28/2027

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 01/29/2026.

Certificate Number: B202601296448555
You may verify this certificate online at https://www.nvsilverflume.gov/home

FRANCISCO V. AGUILAR
Secretary of State

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site VALLEY SPECIALTY PHARMACY

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH04768

Physical Address 3900 W CHARLESTON BLVD STE 130

City LAS VEGAS State _____ Zip 89102

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-359-0985 Website _____

Licensing Company Email INFO.VALLEYRX@GMAIL.COM

Section 2: Personal Information

First LEYDI Middle DEL PILAR Last DIAZ ECHEVARRIA

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City LAS VEGAS State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
DURANGO HIGH SCHOOL		AUG 2003- MAY2007	
Address	City	State	Zip
7100 W. Dewey Drive	LAS VEGAS	NV	89113
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			
School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF RENO		MAY 2019 TO MAY2021	
Address	City	State	Zip
1664 N. Virginia St.	RENO	NEVADA	89557
Diploma/Degree obtained, if any			
MASTER OF SOCIAL WORK			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
FEB 2022 PRESENT	[redacted]	LAS VEGAS	NV	[redacted]
FEB 2020 TO 2022	[redacted]	LAS VEGAS	NV	[redacted]
2017 TO 2020	[redacted]	LAS VEGAS	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
HARMONY MENTAL HEALTH			JUNE 2021 TO PRESENT
Business Address	**City**	**State**	**Zip**
2820 W CHARLESTON BLVD	LAS VEGAS	NV	89102
Phone	**Title**		
7023016667	OWNER		
Description of Duties			
ADMINSTRATIVE AND CLINICAL WORK			

Business Name			From - To (MM/YY – MM/YY)
LABANTE COUNSELIGN SERVICES			2024 TO 2026
Business Address	**City**	**State**	**Zip**
4580 S EASTERN AVE	LAS VEGAS	NV	89113
Phone	**Title**		
725-314-8472	THERAPIST		
Description of Duties			
CLINICAL WORK			

Business Name			From - To (MM/YY – MM/YY)
NORTH VISTA HOSPITAL			2015 TO 2021
Business Address	**City**	**State**	**Zip**
1409 E LAKE MEAD BLVD	LAS VEGAS	NV	89031
Phone	**Title**		
7026497711	CASE MANAGER		
Description of Duties			
DISCHARGE PLANNING			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

8·27·2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

LEYDI D DIAZ ECHEVARRIA

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/27/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Leydi D. Diaz Echevarria, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

8·27·2026

Date

Subscribed and Sworn to before me this 27th day of August, 2026

Notary Public Signature

JENNIFER CHAMPEAU
Notary Public, State of Nevada
No. 12-8626-1
My Appt. Exp. Oct. 27, 2028

(Seal)

TEXAS STATE BOARD OF PHARMACY

May 29, 2026

James A. Belvin
[redacted]
Las Vegas, Nevada [redacted]
Email: [redacted]

RE: James Alvis Belvin, R.Ph. (Texas Pharmacist License #19413)

Dear James A. Belvin:

On May 28, 2026, the Texas State Board of Pharmacy (TSBP) received your request for information regarding the above-described licensee.

We have enclosed documents responsive to the request.

Please note, James A. Belvin, R.Ph. (Texas Pharmacy License #19413) has been in compliance since 2006.

The Texas State Board of Pharmacy would like to request your assistance in assessing the customer service you received. We appreciate your time and input. Please use https://www.surveymonkey.com/r/WYGCJKS to access the survey.

If you need additional information, please contact Sandra Chatham, Senior Administrative Assistant, at (512) 305-8073.

Sincerely,

Open Records
Texas State Board of Pharmacy

AGREED BOARD ORDER #H-05-006-A

RE: IN THE MATTER OF
JAMES ALVIS BELVIN
(PHARMACIST LICENSE #19413)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy the matter of pharmacist license number 19413 issued to James Alvis Belvin, 2406 East Mockingbird Lane, Apartment E5, Victoria, Texas 77904-2302; Date of Birth: November 12, 1942.

By letter dated April 6, 2005, the Texas State Board of Pharmacy gave preliminary notice to James Alvis Belvin of its intent to take disciplinary action with respect to pharmacist license number 19413 held by James Alvis Belvin as a result of an investigation which produced evidence indicating that James Alvis Belvin may have violated:

> Section 565.001(a)(1), (2), (12), and (13) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Subtitle J (Vernon 2003);
>
> Section 281.7(a)(12), (13), and (29)(A); Section 291.31(1), (17), and (18); Section 291.32(a)(2)(I); Section 291.32(c)(1)(E) and (F); Section 291.32(c)(2)(B), (C) and (D); and Section 295.3 of the Texas Pharmacy Rules of Procedure, 22 TEX. ADMIN. CODE (2004); and
>
> Section 431.003; Section 431.021(a), (b) and (r); and Section 431.112(a)(1) of the Texas Food Drug and Cosmetic Act, TEX. HEALTH AND SAFETY CODE ANN. (Vernon 2001), in that, allegedly:

COUNTS

On or about May 18, 2004, James Alvis Belvin, while acting as an employee (pharmacist-in-charge) of H.E.B. Pharmacy #434, 101 Calhoun Plaza, Port Lavaca, Texas 77979, dispensed 28 Doxycycline 500 mg capsules to patient L.J., a woman who was breastfeeding a newborn, on a new written prescription calling for 28 Dicloxacillin 500 mg capsules. The prescription bottle was labeled 28 Dicloxacillin 500 mg capsules. The mistake was discovered by the patient before any of the incorrect medication was ingested. The prescription was assigned prescription #6872609.

By letter dated April 6, 2005 James Alvis Belvin was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By his signature on this Order, James Alvis Belvin neither admits nor denies the truth of the matters previously set out in this Order, agrees that the Texas State Board of Pharmacy has jurisdiction in this matter and waives the right to informal conference, to notice of hearing, to a formal administrative hearing, and to judicial review of this Order.

James Alvis Belvin understands that any failure to comply with the terms of this Order is a basis for discipline under the Texas Pharmacy Act.

Should this Order not be accepted by the Board, it is agreed that neither the presentation of the Order to the Board nor the Board's consideration of the Order, will be deemed to have unfairly or illegally prejudiced the Board or its individual members and, therefore, will not be grounds for precluding the Board or any individual member of the Board from further participation in proceedings related to the matters set forth in the Order.

James Alvis Belvin agrees to the entry of an Order disposing of the need for further disciplinary action in this matter and further agrees to comply with the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Texas State Board of Pharmacy does hereby ORDER that pharmacist license number 19413 held by James Alvis Belvin (hereinafter referred to as "Respondent") shall be, and such license is, hereby reprimanded.

It is further ORDERED that Respondent shall obtain fifteen (15) hours of continuing education with a portion of such hours relating to the prevention of dispensing errors, which shall be in addition to the hours of continuing education required for renewal. Respondent shall submit proof of completion of the continuing education hours to the Texas State Board of Pharmacy, Enforcement Division, within one (1) year of the entry of this Order. All continuing education must be in compliance with the continuing education requirements set forth in Section 295.8 of the Texas Pharmacy Rules, and must be completed after the entry of this Order and before one (1) year after the entry of this Order.

It is finally ORDERED that failure to comply with any of the terms and conditions in this Order constitutes a violation and shall be grounds for further disciplinary action against the Texas pharmacist license held by Respondent.

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 10th day of May, 2005.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

James Alvis Belvin, R.Ph.

Kerstin E. Arnold, General Counsel
Texas State Board of Pharmacy

S:\Attorneys\PNLs\Belvin_ABOmo.doc

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

JAMES A. BELVIN, R.Ph.,
Certificate of Registration No. 9659,

EXPRESS DRUG MART,
Certificate of Registration No. PH0910

Respondents.

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

Case No. 97-035A-RPH-S
Case No. 97-036A-RPH-S
Case No. 97-044A-RPH-S

Case No. 97-035B-RPH-S
Case No. 97-036B-RPH-S
Case No. 97-044B-RPH-S

THIS MATTER was heard by the Nevada State Board of Pharmacy (hereinafter Board) at its regular meeting on January 21, 1998 in Las Vegas. The Board was represented by Louis Ling, Deputy Attorney General. Respondent Belvin represented himself, and Respondent Express Drug Mart was represented by Dan Hopkins. Based on the testimony and documents presented as well as the public records in the possession and control of the Board, the Board issues the following Findings of Fact, Conclusions of Law, and Order:

FINDINGS OF FACT

1. Mr. Belvin, Mr. Hopkins, and Staff stipulated that the facts as alleged in the Notice of Intended Action and Accusation in this matter were true and correct and that four exhibits would be admitted into evidence. Based upon the testimony, admissions, and evidence at hearing, the following are found to be the facts of this case.

2. Mr. Hopkins is the owner of Express Drug Mart, which is the only pharmacy in Overton, Nevada. Mr. Belvin is the only pharmacist employed at Express Drug Mart.

3. In the period of April through August 1997, Mr. Belvin made three pharmacy errors that resulted in complaints to the Board. In the first error, Mr. Belvin filled a

prescription for amitriptyline 25 mg. with amitriptyline 50 mg. The patient discovered the error before ingesting any of the incorrect medication. In the second error, Mr. Belvin filled a prescription for Lotensin 10 mg. with Lotensin 20 mg. The patient ingested the incorrect medication and complained of swelling i his legs and feet. In the third error, Mr. Belvin mislabeled a prescription for Imitrex 50 mg. so that the directions for use stated "Take 2 tablets at onset of headache..." rather than "Take 1 tablet at the onset of headache..." The patient ingested the drug according to the incorrect directions and complained of lightheadedness, dizziness, and weakness. In all three instances, Mr. Belvin admitted in written statements to Staff that he had committed the errors.

3. In addition to the above three instances, Mr. Belvin had received a letter dated October 16, 1997 admonishing him regarding two additional incidents where he had misfilled prescriptions that had not been ingested by the patients.

4. At hearing, Mr. Belvin and Mr. Hopkins explained the measures they had taken as a result of the complaints in this matter. This Board is satisfied that if the measures detailed by Mr. Belvin and Mr. Hopkins are consistently implemented, then the safety, efficiency, and accuracy of the pharmacy and Mr. Belvin's practice should be greatly improved.

CONCLUSIONS OF LAW

1. The Nevada State Board of Pharmacy has jurisdiction over this matter because Respondent Express Drug Mart is a pharmacy registered with the Board and Respondent Belvin is a pharmacist licensed by the Board.

2. In incorrectly filling two patient's prescriptions, Mr. Belvin violated NRS 639.210(4) and NAC 639.945(1)(i).

3. In incorrectly labeling a patient's prescription, Mr. Belvin violated NRS 639.210(4) and NAC 639.945(1)(d) and (i).

4. In being repeatedly negligent as was evidenced by the three prescription errors that are the subject of this action, Mr. Belvin violated NRS 639.210(4) and (16) and NAC 639.945(1)(i).

5. In owning and operating the pharmacy in which Mr. Belvin committed the above errors, Express Drug Mart violated NRS 639.210(4) and 639.266 and NAC 639.945(1)(d) and (i) and (2).

ORDER

Based upon the foregoing, the Board hereby orders the following:

1. Mr. Belvin and Express Drug Mart shall develop and produce a written policies and procedures manual. This manual shall detail the various policies and procedures to be used by all Express Drug Mart employees in the handling and filling of prescriptions, the ordering and handling of drugs, the handling of telephone calls, the handling of third-party transactions and Medicaid and Medicare transactions, etc. A copy of the policy and procedures manual, including a signature sheet showing that all employees of Express Drug Mart have read and understood the manual, must be received by the Board office no later than April 15, 1998. The Board shall review the manual at its meeting on April 29 and 30, 1998 and shall either approve the manual or shall suggest additional changes that must be made before approval.

2. Failure by either Respondent to comply with any term or condition of this Order may result in additional discipline, up to and including revocation of that Respondent's license.

Signed and effective this 30th day of January, 1998.

Larry L. Pinson, President
Nevada State Board of Pharmacy

CONCLUSION

Action Taken

1. Policy and procedure program implemented which includes:
   A. Ethics, fraud, waste, and abuse
   B. Compliance with third-party rules and regulations
   C. Best and safe practice programs implemented including:
      - Best procedure for a safe workflow including patient counseling
      - Strict compliance with laws regulating controlled substances
2. Currently, I am in compliance with the Nevada State Board of Pharmacy and Texas State Board of Pharmacy (Board Orders). I continue to be in good standing with both NSBP and TSBP as of this date.

Sincerely,

James A. Belvin

Date: 6/17/2026

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Valley Specialty Pharmacy

Pharmacy/Wholesaler License # (if applicable)

Physical Address 3900 W Charleston Blvd Ste #130

City Las Vegas State NV Zip 89102

Mailing Address (if different from physical address)

City Las Vegas State NV Zip 89102

Telephone 7023590985 Website INFO.Valleyrx@Gmail.com

Licensing Company Email

Section 2: Personal Information

First James Middle Alvis Last Belvin

Alias(es, nicknames, name changes, etc.) Jim

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zi[redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	N/A	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	N/A	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	N/A	

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Texas Southern University			From - To (MM/YY – MM/YY): 69-71
Address: 3100 Cleburne St.	City: Houston	State: Tx	Zip: 77004
Diploma/Degree obtained, if any: BS Pharmacy			
School Name: Howard Payne University			From - To (MM/YY – MM/YY): 61-65
Address: 1000 Fisk St.	City: Brownwood	State: Tx	Zip: 76801
Diploma/Degree obtained, if any:			
School Name: Brownwood High School			From - To (MM/YY – MM/YY): 58-61
Address: 2100 Slayden ST	City: Brownwood	State: Tx	Zip: 76801
Diploma/Degree obtained, if any:			
School Name: N/A			From - To (MM/YY – MM/YY):
Address:	City:	State:	Zip:
Diploma/Degree obtained, if any:			
School Name:			From - To (MM/YY – MM/YY:
Address:	City:	State:	Zip:
Diploma/Degree obtained, if any:			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1/2023 —	[redacted]	Las Vegas	NV	[redacted]
12/2014 – 1/2023	[redacted]	Pahrump	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Pahrump Care Pharmacy			From - To (MM/YY – MM/YY): 2025–
Business Address: 1500 State 372 E.	City: Pahrump	State: NV	Zip: 89048
Phone: 347 2793085	Title: Per-diem		Number of Employed Hours: 120hr 8hr / Per diem
Description of Duties: Verify & dispense Prescriptions / Record Keeping Counsel Patients Supervise Techs			

Business Name: Preferred PHmcy			From - To (MM/YY – MM/YY): 2024- 2025
Business Address: 2202 W Charleston	City: Las Vegas	State: NV	Zip: 89102
Phone: Permanently Closed	Title: STAFF Pharmacist Per diem		Number of Employed Hours: 700+
Description of Duties: Verify & Dispense Prescriptions for Delivery / Supervise Techs			

Business Name: Drug Emporium Tyler			From - To (MM/YY – MM/YY): 2008- 2014
Business Address: 5614 S. Broadway / 2321 W. Loop 281	City: Tyler & Longview	State: TX	Zip: 75703
Phone: 9032970966	Title: PIC / STAFF		Number of Employed Hours: 17,400
Description of Duties: Verify & Dispense Prescriptions Provide Immunizations Counsel Patients Record Keeping Supervision of Techs			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, James Belvin, certify that as the designated representative for Valley Specialty Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

James Belvin
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Sep 16, 2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

James Belvin
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Sep 16, 2026
Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, James Belvin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Sep 16, 2026
Date

Subscribed and Sworn to before me this 16 day of Sept, 2026

Notary Public Signature

SHAROL L WILLIAMS
Notary Public - State of Nevada
County of Clark
Appt. No. 12-9146-1
My Appt. Expires: September 26, 2028

(Seal)

10

10A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

4

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH N/A	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Refer to cover letter.	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: N/A ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: Refer to cover letter.

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☒ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: LillyDirect Pharmacy, LLC

Physical Address: 1555 S. Harding St., Ste. 171-B68

City: Indianapolis State: IN Zip: 46221

Mailing Address (if different from physical address): 1555 S. Harding St., Ste. 171-B68

City: Indianapolis State: IN Zip: 46221

Telephone: 317-276-0600 Toll Free # (NAC 639.708, NRS 639.23286): 844-559-3471

Fax: 877-317-0610 Contact Email: pharmacy_compliance@lists.lilly.com

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Joshua Wheat

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 25196

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Joshua Wheat	NV Pharmacist Registration #: 25196
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name: N/A	Credentials:	%:
Name: N/A	Credentials:	%:
Name: N/A	Credentials:	%:
Name: N/A	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): Eli Lilly and Company

Corporation Name: LillyDirect Pharmacy, LLC

Mailing Address: 1555 S. Harding St., Ste. 171-B68

City: Indianapolis State: IN Zip: 46221

Telephone: 317-276-0600 Email: pharmacy_compliance@lists.lilly.com

Contact Person Name: Brent Danner

Date of SEC Registration: 1952 | SEC Registration Number: 59478 | Stock Exchange Symbol: LLY

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☒ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the AVP of Pharmacy (title) for LillyDirect Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Brent Danner

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

3/25/2026

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Brent Danner hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the AVP of Pharmacy (title) for LillyDirect Pharmacy, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 25 day of March, 20 26

Notary Public

NOTARY PUBLIC SEAL STATE OF INDIANA
PAULETTE M STULL
My Commission Expires
February 24, 2030
Commission Number NP0651308
Johnson County

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brent Danner

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

3/25/2026

Date

Board Use Only	Date Received: 4/2/26	Amount: $500 CK 1000002694 ✓

LillyDirect Pharmacy, LLC
1555 S. Harding St., Ste. 171-B68, Indianapolis, IN 46221

- List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)
  - Jonathan Haug - President
  - Christopher Anderson - Secretary
  - Jonathan Groff - Assistant Secretary
  - Steffanie Lim-Ho - Treasurer
  - Katie Lodato - Assistant Treasurer
  - Brent Danner - AVP of Pharmacy

- List the top four stockholders and their percent ownership. NRS 639.231(3)
  - Eli Lilly and Company - 100% owner

- List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)
  - Eli Lilly and Company - 100% owner

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "LILLYDIRECT PHARMACY, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FIFTH DAY OF MARCH, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "LILLYDIRECT PHARMACY, LLC" WAS FORMED ON THE NINTH DAY OF DECEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charumi Patibanda-Sanchez, Secretary of State

10032016 8300

SR# 20261382199

Authentication: 203458660

Date: 03-25-26

You may verify this certificate online at corp.delaware.gov/authver.shtml

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "BALANCE PHARMACY SERVICES, LLC", CHANGING ITS NAME FROM "BALANCE PHARMACY SERVICES, LLC" TO "LILLYDIRECT PHARMACY, LLC", FILED IN THIS OFFICE ON THE FIFTEENTH DAY OF MAY, A.D. 2025, AT 10:16 O`CLOCK A.M.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

10032016 8100
SR# 20252310111

3499
Authentication: 203700062
Date: 05-15-25

State of Indiana
Office of the Secretary of State

CERTIFICATE OF EXISTENCE

To Whom These Presents Come, Greeting:

I, DIEGO MORALES, Secretary of State of Indiana, do hereby certify that I am, by virtue of the laws of the State of Indiana, the custodian of the corporate records and the proper official to execute this certificate.

I further certify that records of this office disclose that

ELI LILLY AND COMPANY

duly filed the requisite documents to commence business activities under the laws of the State of Indiana on January 17, 1901, and was in existence or authorized to transact business in the State of Indiana on March 02, 2026.

I further certify this Domestic For-Profit Corporation has filed its most recent report required by Indiana law with the Secretary of State, or is not yet required to file such report, and that no notice of withdrawal, dissolution, or expiration has been filed or taken place. All fees, taxes, interest, and penalties owed to Indiana by the domestic or foreign entity and collected by the Secretary of State have been paid.

In Witness Whereof, I have caused to be affixed my signature and the seal of the State of Indiana, at the City of Indianapolis, March 02, 2026

Diego Morales

DIEGO MORALES
SECRETARY OF STATE

183025-143 / 20264930884
All certificates should be validated here: https://bsd.sos.in.gov/ValidateCertificate
Expires on April 01, 2026.

Pharmacy
402 W. Washington Street
Indiana Government Center South, Room W072

Indianapolis, IN 46204

FACILITY
Balance Pharmacy Services, LLC
1555 S. Harding St., Ste. 171-B68
Indianapolis IN 46221
Phone: 3172760600
Owner:
Ownership Type:

LICENSE
License No:
Profession: Pharmacy
License Type: Pharmacy
1555 S. Harding St., Ste. 171-B68
Indianapolis IN 46221
Phone: 3172760600

Inspection Type:	Pharmacy Inspection
Inspection Date:	5/8/2025
Result:	Pass

Remarks: New pharmacy inspection approved, please issue permit as soon as possible. Also, pharmacy does not perform any compounding or immunizations nor does it dispense any REMS drugs or controlled substances. Sections of this inspection are not applicable because they do not apply to the business model for this pharmacy. Please let me know if you have any questions.

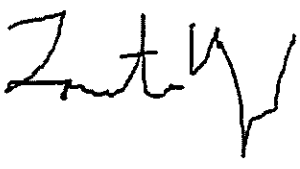
Checklist Results
Pharmacy General Information
Absence of Pharmacist
Staff/Personnel
Pharmacy Equipment/Security
References
Automated Medication Systems & Automatic Counting
AMS Automated Packaging Systems
Drug storage/labeling/destruction
Dispensing/Records Retention
Fax/e-prescribing/Transfers
Remote Order Entry and Centralized Processing
Generic Substitution
Controlled Substances
DEA Forms
INSPECT
Sterile Compounding: Policies and Procedures
Sterile Compounding: Engineering Controls
Sterile Compounding: Personnel
Sterile Compounding: Labeling/Documentation
Non-sterile Compounding
Remote Locations (Type II only)

Quality-Related Events/Patient Own Medications
Special Medications
Immunization Rule
Patient Confidentiality (HIPAA)
Prescription Audit

As the undersigned representative of the licensee, I affirm that the information provided during the inspection is true and accurate to the best of my knowledge. I understand that the licensee is responsible for the legal operations of the facility and I am executing this inspection form as, or on behalf of the licensee.

The alleged violator has voluntarily entered into an Opportunity to Correct Plan with the Indiana Professional Licensing Agency (PLA). Pursuant to IC 4-21.5-2.5-7, the alleged violator enters into a written Corrective Plan to correct the alleged violation(s) set forth above before the agency institutes an enforcement action which may include the filing of a Consumer Complaint with the Office of the Indiana Attorney General. Upon notice that the alleged violation(s) has been corrected, this Agency shall re-inspect not more than thirty (30) days after to determine if you have substantially complied with the applicable rule or state statute. If subsequent inspection identifies a failure to address previous violations the facility will "fail" the inspection and additional enforcement actions may be initiated against licensure.

In order to avoid additional enforcement action, the alleged violator must submit the Corrective Plan within five (5) business days after the initial inspection. A plan of corrective action can be either emailed to PLACompliance@pla.in.gov, or mailed to: Indiana Professional Licensing Agency, Attn: Compliance Division, 402 W. Washington St. RM W072, Indianapolis, IN 46204.



5/8/2025 12:09:54 PM



Signature of Inspector | Date/Time | Signature of Owner/Representative

Pharmacy
402 W. Washington Street
Indiana Government Center South, Room W072

Indianapolis, IN 46204

FACILITY
Balance Pharmacy Services, LLC
1555 S. Harding St., Ste. 171-B68
Indianapolis IN 46221
Phone: 3172760600

LICENSE
License No:
Profession: Pharmacy
License Type: Pharmacy

Inspection Type:	Pharmacy Inspection
Inspection Date:	5/8/2025
Result:	Pass

Remarks: New pharmacy inspection approved, please issue permit as soon as possible. Also, pharmacy does not perform any compounding or immunizations nor does it dispense any REMS drugs or controlled substances. Sections of this inspection are not applicable because they do not apply to the business model for this pharmacy. Please let me know if you have any questions.

Checklist Results

Pharmacy General Information	
1.1 Type of Inspection	New Store (NS)
1.5 County	Marion
1.6 Telephone number	3172760600
1.9 Controlled Substance Registration (CSR) number	N/A
1.11 Controlled Substance Registration expiration date	N/A
1.12 DEA registration number	N/A
1.14 DEA expiration date	N/A
1.15 Qualifying pharmacist name	N/A
1.16 Name of pharmacist-of-record at the time of inspection	Tia Thomas
1.17 Name of district manager	Brent Danner
1.18 E-mail of district manager	bdanner@lilly.com
1.19 Size of company/number of pharmacies nationwide	Independent
1.20 Average number of prescriptions filled daily	N/A
1.21 Days and Times of operation?	Tues, Wed, & Thur. 10-4
1.22 Is pharmacy open 24 hours a day?	No

Absence of Pharmacist	
2.1 If institutional pharmacy, how are drugs obtained for patient use when pharmacy is closed?	N/A
2.2 If institutional pharmacy, is a pharmacist reconciling drug removal against the order within 24 hours?	N/A
2.3 If institutional pharmacy employs after hours pharmacy access, does only one (1) supervisory licensed nurse per shift have access?	N/A
2.3a - Is the proper drug information recorded as required by law?	N/A
2.3b - Is a copy of the drug order left in the pharmacy?	N/A
2.4 Excluding after hours access by a supervisory nurse in an institutional pharmacy, is the licensed area unoccupied when the pharmacist is absent?	N/A
2.5 If institutional pharmacy, is there an emergency access policy for closed pharmacy?	N/A
2.6 If retail pharmacy, does prescription department have appropriate signage for pharmacist absence?	N/A

3.1 How many pharmacists are employed by the pharmacy?	1
3.2 How many technicians are employed by the pharmacy?	0
3.2a - Do all technicians possess a valid certification?	N/A
3.2b - Are any of the certifications on probation?	N/A
3.2c - Are any of the certifications "Valid to Practice While Being Reviewed"?	N/A
3.2d - What training does the pharmacy require of technicians?	N/A
3.2e - Are all technicians wearing a nametag stating their profession?	N/A
3.2f - Are all technicians engaging in legally permitted activities	N/A
3.3 How many interns are employed by the pharmacy?	0
3.3a - Do all interns possess a valid registration?	N/A
3.3b - Are any of the registrations on probation?	N/A
3.3c - Are any of the registrations "Valid to Practice While Being Reviewed"?	N/A
3.4 Does the pharmacy have ancillary personnel working in the licensed area?	N/A
3.4a - Are ancillary personnel engaging in permitted activities?	N/A
3.4b - How many ancillary personnel are working in the licensed area at the time of inspection?	N/A
3.5 Are all licenses and certifications properly displayed?	Yes
3.6 Are the pharmacy technician files complete?	N/A
3.7 Is the technician ratio proper (6 to 1)?	N/A
3.8 Do technicians properly answer the telephone stating to the caller they are a technician?	
3.9 Does staff properly make an offer for counseling?	

Pharmacy Equipment/Security	
4.1 Is the pharmacy area properly equipped, and include the following?	Yes
4.1a - Scale (if performing non-sterile compounding)?	N/A
4.1b - proper documentation from Department of Weights and Measures	N/A
4.1c - refrigeration	N/A
4.1d - sink (proper sewage outlet)	Operational
4.1e - hot and cold water	Operational
4.1f - stationary / immobile	Yes
4.1g - well lit	Yes
4.1h - ventilated	Yes
4.1i - sanitary	Yes
4.1j - proper temperature	Yes
4.3 Is the pharmacy properly secured?	Yes
4.3a - Does the pharmacy have a motion detector?	No
4.3b - Does the pharmacy have an alarm?	No
4.3c - Does the pharmacy have a camera(s)?	No
4.3d - Does the pharmacy have locking doors?	Yes
4.3e - Does the pharmacy have a panic button?	No
4.3g - List any additional security measures.	N/A
4.4 What is the method of entry into the pharmacy?	Security Card
4.5 Is the drive thru secure?	N/A
4.6 When closed, do non-authorized personnel have access to the perscription department?	No
4.7 What are the number of entrances to the pharmacy?	1

References	
5.1 How does the pharmacy access current Indiana pharmacy law?	internet
5.1e - Does the pharmacy utilize other on-line subscriptions (Micromedex, Clinical Pharmacology, etc)?	Yes
5.1f - If pharmacy uses on-line service, are employees able to access?	Yes
5.2 For sterile compounding, does the pharmacy have at least one of the following reference materials?	N/A
5.2a - The Handbook on Injectable Drugs	N/A
5.2b - The King's Guide to Parenteral Admixtures	N/A
5.2c - another Board approved, printed or electronic database	Yes

6.1 Does the pharmacy utilize a counting device(s)?	No
6.1a - Are policies and procedures in place?	N/A
6.1b - Are maintenance protocols followed and documented?	N/A
6.1c - Are quality assurance protocols followed and documented?	N/A
6.1d - Is there proper documentation of drugs dispensed?	N/A
6.2 Does the pharmacy utilize a cabinet(s)?	No
6.2a - Are policies and procedures in place?	N/A
6.2b - Are maintenance protocols followed and documented?	N/A
6.2c - Are quality assurance protocols followed and documented?	N/A
6.2d - Is the cabinet only accessible by authorized personnel?	N/A
6.2e - Is there proper documentation of drugs dispensed?	N/A
6.3 Does the pharmacy utilize an automated will-call machine?	No
6.3a - Are policies and procedures in place?	N/A
6.3b - Are maintenance protocols followed and documented?	N/A
6.3c - Are quality assurance protocols followed and documented?	N/A
6.3d - Is there proper documentation of drugs dispensed?	N/A
6.4 Does the pharmacy utilize another form of automation?	No
6.4a - Are policies and procedures in place?	N/A
6.4b - Are maintenance protocols followed and documented?	N/A
6.4c - Is there proper documentation for drugs dispensed?	N/A
6.4d - Are quality assurance protocols followed and documented?	N/A

AMS Automated Packaging Systems	
7.1 Is the pharmacy properly logging the lot and expiration date for the drugs?	N/A
7.2 Are the drugs properly labeled if repackaged?	N/A
7.3 Do the drugs properly fit in the bubble pack?	N/A
7.4 Does the pharmacy have written policies and procedures of operation?	N/A
7.5 Has the automation been inspected and approved by the Pharmacy Board?	N/A
7.6 Does the pharmacy have a written plan for recovery in an emergency that includes the following?	N/A
7.6a - Planning and preparation for an emergency	N/A
7.6b - Procedures for response to an emergency	N/A
7.6c - Procedures for notifying the Board, patients, and those they have contracts with	N/A
7.6d - Procedures for maintenance and testing of recovery plan	N/A
7.7 Does the pharmacy have a written policy for quality assurance that includes the following?	N/A
7.7a - Testing and accuracy of the system on a biannual basis	N/A
7.7b - Retaining all quality documents for two (2) years	N/A
7.7c - Continuous monitoring of the system	N/A
7.7d - Reporting recurring errors to the Board	N/A
7.7e - What is the protocol for measuring effectiveness of AMS?	N/A
7.8 Is all pharmacy personnel with access to AMS trained in the pharmacy's policies and procedures?	N/A
7.9 Does the pharmacy have a written program for preventative maintenance of the system?	N/A

Drug storage/labeling/destruction	
8.2a - If yes, provide detailed information.	N/A
8.5 Does the pharmacy properly maintain a logbook for schedule V controlled substances dispensed without a prescription?	N/A
8.6 Does the pharmacy properly maintain a logbook for syringes dispensed without a prescription?	N/A
8.7 Is the pharmacy properly reporting all sales of pseudoephedrine products to the NPLEx tracking system?	N/A
8.7a - How are ephedrine and pseudoephedrine products stored?	N/A
8.8a - If yes, is storage and distribution in accordance with federal regulations?	N/A
8.9 Does the pharmacy have current pseudoephedrine purchasing limits posted?	N/A

9.2 What type of software application does the pharmacy use?	Under board review; pending final approval
9.3 Does the pharmacy scan a hard copy of prescriptions?	N/A
9.4 How does the pharmacy back up files?	Pending final approval
9.5 Does the pharmacy have internet access?	Yes
9.6 How does the pharmacy maintain daily dispensing records?	Board approved system
9.7 Does the pharmacy retain these records for five (5) years?	Yes
9.10 What type of filling system is used for prescriptions?	N/A
9.11a - If yes, where are the records stored?	On site server/database
9.11b - Is the data readily retrievable by the pharmacy?	Yes
9.11c - Who may access the data?	Only authorized personnel

Fax/e-prescribing/Transfers	
10.1 Is the facsimile machine in the prescription department or a nonpublic area of the pharmacy?	Yes
10.1a - Does the facsimile prescription contain all information required by law (IC 25-26-13-2)?	N/A
10.1b - Excluding Rule 31 exceptions, have schedule II controlled substances been dispensed pursuant to a faxed prescription?	N/A
10.1c - Does original presciption have "valid only if transmitted by facsimile machine" on its face?	N/A
10.1d - If the facsimile does not contain required information, has the pharmacist verified the prescription with appropriate documentation (i.e., reduced to writing)?	N/A
10.2 Do all e-presciptions contain all of the information required by law?	N/A
10.2a - Is the Electronic Data Intermediary (EDI) approved by the Board of Pharmacy?	N/A
10.2b - Does the pharmacy maintain policies and procedures to ensure security of all information?	N/A
10.2c - Does the manual address the safety of the prescription?	N/A
10.2d - Does the manual address the safety of the practitioner's identity and privacy?	N/A
10.2e - Does the manual address the safety of the patient's identity, privacy and confidentiality?	N/A
10.3 If observed, are pharmacists properly processing transfers?	
10.3a - Is prescription pad form completed on transfer?	N/A
10.3b - On transfer out, is all required information recorded on the invalidated prescription?	N/A
10.3c - On transfer in, is all required information recorded on the transferred prescription?	N/A
10.3d - Does the pharmacy print out a "transfer in" and "transfer out" report to confirm it has been transmitted?	N/A

Remote Order Entry and Centralized Processing	
11.1 Is the pharmacy performing or contracting centralized processing services?	No
11.2 Do the parties involved have the same owner or a written contract?	Same owner
11.3 Does the pharmacy have a written policies and procedures manual for performing or contracting CPS?	N/A
11.3a - Does the manual address how the parties will comply with federal and state laws and regulations?	Yes
11.3b - Does the manual address maintenance records to identify the responsible pharmacist(s) in the dispensing and counseling processess?	Yes
11.3c - Does the manual address a mechanism for tracking the prescription drug order during each step in the dispensing process?	Yes
11.3d - Does the manual address a mechanism to identify on the prescription label all pharmacies involved in dispensing the prescription drug order?	N/A
11.3e - Does the manual address the provision of adequate security to protect the product integrity?	Yes
11.3f - Does the manual address the provision of adequate security to prevent the illegal use or disclosure of protected health information?	Yes
11.3g - Does the manual address the maintenance of a continuous quality improvement program for centralized prescription processing pharmacy services?	Yes

Generic Substitution

13.1 Does the pharmacy maintain a perpetual inventory for controlled substances?	N/A
13.1a - If yes, which controlled substance schedules are inventoried perpetually?	N/A
13.1b - If no, what is the date of last biennial inventory (Type II facilities and facilities without controlled substances are exempt).	N/A
13.1c - Is inventory within 2 years of last biennial inventory?	N/A
13.1e - Is the inventory signed by the pharmacist with date and time?	N/A
13.1f - Is the inventory complete?	N/A
13.1g - If incomplete, provide details.	N/A
13.2a - What is the method of storage?	N/A
13.2b - If method of storage is improper, provide explanation.	N/A
13.3 Who is your reverse distributor for destruction of controlled substances?	N/A
13.3a - Does the pharmacy properly maintain reverse distribution receipts?	N/A
13.4 Are controlled substance records maintained separately from all other pharmacy records?	N/A
13.5 Who is your primary Wholesale Drug Distributor for Controlled Substances?	N/A

DEA Forms	
14.2d - Are DEA Form 222's properly executed?	N/A
14.2j - Does the pharmacy have power of attorney that enables employees to place the order?	N/A
14.3 Does the pharmacy maintain copies of DEA Form 106 (theft and loss), if applicable?	N/A
14.4 Does pharmacy have DEA Form 41 on file if destroyed with witness of special agent or compliance officer?	N/A
14.5 Has the pharmacy reported theft of controlled substances to DEA within one (1) business day?	N/A
14.6 Have all thefts/losses been reported to the Pharmacy Board?	N/A

INSPECT	
15.1 Is the pharmacy currently reporting all controlled substance prescription data to INSPECT within seven (7) days of dispensing to a patient?	N/A
15.1a - If yes, provide verification of previous two submissions. Enter "Automatic Submission", if applicable.	Zero reports

Sterile Compounding: Policies and Procedures	
16.2e - Do the quality assurance procedures cover sterility testing or monitoring, if employed, in the case of routine bulk compounding from nonsterile chemicals-high risk level compounding?	N/A

Sterile Compounding: Engineering Controls	
17.2a - Total number of PEC's used	0
17.2b - Do the PEC's maintain ISO class 5 environment during in-use activity?	N/A
17.3 Are PECs located within appropriate secondary engineering controls?	N/A
17.4 Do secondary engineering controls (buffer area, ante area) maintain appropriate ISO classification?	N/A
17.5 If using CAI, is it located in an ISO class 7 buffer room?	N/A
17.5a - If no, does pharmacy have proper manufacturer documentation that it can maintain ISO class 5 environment during use?	N/A
17.6 Is appropriate pressure differential or airflow between control environments and the general pharmacy maintained and documented at least every work shift?	N/A
17.7 Is there a cleaning log for the PEC?	N/A
17.8 Is there a daily cleaning log for the counters, floors and work surfaces?	N/A
17.9 Is there a monthly cleaning log for the walls, ceiling and shelving?	N/A
17.10 Is there a cleaning log for the cleaning of BSC between uses if preparing both hazardous and non-hazardous preparations?	N/A
17.11 Are there proper containers for disposal of waste?	N/A
17.12 Does the pharmacy have records of necessary environmental sample testing maintained for two (2) years?	N/A
17.13 Does the pharmacy have total particle counts of each ISO classified area - performed not less than every six (6) months and when PEC is moved?	N/A
17.14 Does the pharmacy have volumetric air sampling for microorganisms in each ISO classified area - performed not less than every six (6) months?	N/A

18.1 Is there documentation of all personnel preparing sterile pharmaceuticals?	N/A
18.2 Is there documentation of all support personnel assisting with sterile pharmaceuticals?	N/A
18.3 Are personnel assessments/competencies related to aseptic technique, garbing, and cleaning/disinfecting performed at least annually?	N/A
18.4 Does the pharmacy have documentation of training and assessment for all personnel engaging in preparation of sterile pharmaceuticals, including support personnel (housekeeping, environmental services) as related to garbing (assessment: observation, gloved fingertip sampling)?	N/A
18.5 Does the pharmacy have documentation of training and assessment for all personnel engaging in preparation of sterile pharmaceuticals, including support personnel (housekeeping, environmental services) as related to aseptic technique (assessment: written test, media-fill test)?	N/A
18.6 Does the pharmacy have documentation of training and assessment for all personnel engaging in preparation of sterile pharmaceuticals, including support personnel (housekeeping, environmental services) as related to cleaning/disinfecting procedures (assessment: observation, surface sampling via contact plates/swabs)?	N/A
18.7 Are personnel engaging in appropriate aseptic technique, garbing, and cleaning/disinfecting at the time of inspection?	N/A

Sterile Compounding: Labeling/Documentation	
19.1 Does the label on the dispensed sterile pharmaceutical contain all information required by law?	N/A
19.2 Does the label have the additional information required if dispensed at home or outside the facility?	N/A
19.3 Is there documentation of patient training by the pharmacists to patients in the home?	N/A
19.4 Are single- and multiple-dose containers (e.g., vials) being properly used and stored with appropriate BUD when applicable?	N/A
19.5 Does the pharmacy have disposable needles, syringes and other supplies needed for aseptic admixture?	N/A
19.6 Does the pharmacy have disinfectant cleaning tools and solutions (i.e. sterile 70 % IPA)?	N/A
19.7 Does the pharmacy have a hand washing agent with antibacterial action?	N/A
19.8 Does the pharmacy have disposable towels or wipes?	N/A
19.9 Does the pharmacy have filters and filtration equipment, if utilized?	N/A
19.10 Does the pharmacy have a hazardous drug spill kit if hazardous drugs are prepared?	N/A
19.11 Does the pharmacy have disposable gowns and gloves?	N/A
19.12 Does the pharmacy have a refrigerator with a thermometer and temperature log?	N/A
19.13 Does the pharmacy have an infusion device, if appropriate?	N/A
19.14 Does the pharmacy have a sink with hot and cold running water, outside of the buffer area?	N/A
19.15 Does the pharmacy use a computer system to monitor 797 compliance? (i.e. Simplify 797)	N/A

Non-sterile Compounding	
20.2 Does the pharmacy have an affiliation with a professional compounding organization?	N/A
20.2a - If yes, which one?	N/A
20.3 Does the regular pharmacy software application produce formula sheets?	N/A
20.4 Does the pharmacy record lot numbers and expiration dates of medications utilized during non-sterile compounding?	N/A
20.5 Does the pharmacy label compounded pharmaceuticals in accordance with USP 795?	N/A
20.6 Does the pharmacy check expiration dates of compounding chemicals?	N/A
20.7 Does the pharmacy assign beyond use dates to the compounded pharmaceuticals in accordance with USP 795?	N/A
20.7a - If yes, where does the pharmacy obtain it's information?	N/A
20.8a - If technicians are preparing compounded pharmaceuticals, how were they trained?	N/A
20.8b - Does the pharmacy submit sample compounds to outside testing labs for verification of the product strength and concentration?	N/A

Remote Locations (Type II only)	
21.1 If hospital (Type II) pharmacy, does pharmacy operate remote location(s)?	N/A
21.1a - If yes, how many remote locations?	0
21.2 Does the remote location have a pharmacist present?	N/A
21.3 Is a mechanical device used at the remote location(s)?	N/A
21.4 Is the remote location properly secured?	N/A

22.1 For hospital pharmacies, do policies and procedures include determination of drugs and quantities to be included?	N/A
22.1a - For hospital pharmacies, do policies and procedures include labeling for expiration date?	N/A
22.1b - For hospital pharmacies, do policies and procedures include process for restocking the cart(s) or box(es)?	N/A
22.1c - For hospital pharmacies, do policies and procedures include security measures to prevent unauthorized access?	N/A
22.2 For Type III and Type VI permits, is the list of drugs/quantities included in each kit reviewed at least annually?	N/A
22.2a - Does the exterior labeling of the kit(s) meet the requirements of 859 IAC 1-28.1-9?	N/A
22.2b - Are all drugs contained in the kit(s) labeled as required by 856 IAC 1-28.1-9?	N/A
22.2c - Are controlled substances contained in the kit(s) included in the pharmacy's biennial inventory?	N/A
22.2d - Is the nurse responsible for removing drugs from the kit recording the information as required by 856 IAC 1-28.1-9?	N/A
22.2e - Is the restocking and resealing of the kit(s) being performed by the pharmacy?	N/A

Quality-Related Events/Patient Own Medications	
23.1b - Are records of analysis and corrective action available for review?	N/A
23.2b - Are records of analysis and corrective action available for review?	N/A
23.3 Are patient's own medications maintained exclusively in the patient care area or at the bedside?	N/A
23.4 Upon discharge or death, are such medications handled according to 856 IAC 1-28.1-14?	N/A

Special Medications	
24.1 Does the pharmacy report the dispensing of clozapine within five (5) days to the CNR?	N/A
24.1a - Which method does the pharmacy use for reporting the dispensing of clozapine?	N/A
24.2 Has the pharmacy received authorization from the iPLEDGE program to dispense isotretinoin (Accutane)?	N/A
24.2a - Is the MedGuide included with the prescription?	N/A
24.2b - Does the pharmacy have a record of pharmacist training for the iPLEDGE program?	N/A
24.3 Is the authorization number on all prescriptions for Thalomid?	N/A
24.3a - Is the pharmacy registered in the STEPS program for dispensing?	N/A
24.4- Does the pharmacy dispense any other "special medications" with an RDDS program?	N/A
24.5 Does the pharmacy follow proper FDA and manufacturers practices for other "special" medications such as Ticocin?	N/A

Immunization Rule	
25.1 What type of immunizations do pharmacists administer?	N/A
25.2 Does the pharmacy have a Doctor's standing order in place for influenza and/or shingles immunizations?	N/A
25.2a - If administering per a standing order, does the protocol contain all the information required by law?	N/A
25.2b - Is the protocol up to date (renewed annually)?	N/A
25.3 Have all pharmacists administering immunizations completed an ACPE accredited training program?	N/A
25.4 Is the pharmacist CPR certified?	N/A
25.5 Is the pharmacist the only person administering vaccinations within the licensed area?	N/A
25.6 What are the procedures in place to address emergency situations?	N/A
25.7 Does the pharmacy maintain records of adverse event reporting to the necessary physicians and VAERS as required?	N/A
25.8 Does the pharmacy notify the authorizing physician and the individual's primary care physician of immunization administration within 14 days?	N/A

Patient Confidentiality (HIPAA)	
26.1 How does the pharmacy dispose HIPAA trash?	On-site shred
26.1a - Is the dumpster locked and secure?	N/A
26.1b - What is the name of off-site HIPAA vendor?	N/A

Prescription Audit	
27.1 Do all Controlled Substance prescriptions meet Indiana security feature requirements?	N/A
27.2 Do all Controlled Substance prescriptions contain all information required by law?	N/A

understand that the licensee is responsible for the legal operations of the facility and I am executing this inspection form as, or on behalf of the licensee.

The alleged violator has voluntarily entered into an Opportunity to Correct Plan with the Indiana Professional Licensing Agency (PLA). Pursuant to IC 4-21.5-2.5-7, the alleged violator enters into a written Corrective Plan to correct the alleged violation(s) set forth above before the agency institutes an enforcement action which may include the filing of a Consumer Complaint with the Office of the Indiana Attorney General. Upon notice that the alleged violation(s) has been corrected, this Agency shall re-inspect not more than thirty (30) days after to determine if you have substantially complied with the applicable rule or state statute. If subsequent inspection identifies a failure to address previous violations the facility will "fail" the inspection and additional enforcement actions may be initiated against licensure.

In order to avoid additional enforcement action, the alleged violator must submit the Corrective Plan within five (5) business days after the initial inspection. A plan of corrective action can be either emailed to PLACompliance@pla.in.gov, or mailed to: Indiana Professional Licensing Agency, Attn: Compliance Division, 402 W. Washington St. RM W072, Indianapolis, IN 46204.

Signature of Inspector	5/8/2025 12:09:54 PM Date/Time	Signature of Owner/Representative

Indiana Professional Licensing Agency
Indiana Board of Pharmacy
402 W. Washington Street, W072
Indianapolis, IN 46204

Pharmacy

Registration Number	Expire Date
60006990A	12/31/2027

LillyDirect Pharmacy, LLC
1555 S. Harding St
Ste 171-B68
Indianapolis IN 46221

Mike Braun
Governor
State of Indiana

Lindsay M. Hyer
Executive Director
Indiana Professional Licensing Agency

Indiana Professional Licensing Agency
402 W. Washington Street, W072
Indianapolis, IN 46204

Pharmacy

Registration Number	Expire Date
60006990A	12/31/2027

LillyDirect Pharmacy, LLC

Signature _____

State of Indiana

DEMOGRAPHIC INFORMATION

Name: LillyDirect Pharmacy, LLC

Contact Person:

ADDRESS INFORMATION

Line 1: 1555 S. Harding St
Line 2: Ste 171-B68
City/State/Zip: Indianapolis IN 46221
County: Marion

LICENSE INFORMATION

Lic #:	60006990A	Profession:	Pharmacy Board	Type:	Pharmacy	Secondary:	
Status:	Active	Issued:	5/8/2025	Expiration:	12/31/2027	Renewed:	11/17/2025
Method:	Application						

LITIGATION INFORMATION

-

RELATED LICENSES

No Related Licenses

SPECIALTY INFORMATION

No Specialty Information

INSPECTION INFORMATION

Inspection Type: Pharmacy Inspection Report Inspection Date: 5/8/2025 Inspection Grade: Pass

3512

State of Indiana

DEMOGRAPHIC INFORMATION

Name: LillyDirect Pharmacy, LLC

Contact Person:

ADDRESS INFORMATION

Line 1: 1555 S. Harding St
Line 2: Ste 171-B68
City/State/Zip: Indianapolis IN 46221
County: Marion

LICENSE INFORMATION

Lic #:	60006990A	Profession:	Pharmacy Board	Type:	Pharmacy	Secondary:	
Status:	Active	Issued:	5/8/2025	Expiration:	12/31/2027	Renewed:	11/17/2025
Method:	Application						

LITIGATION INFORMATION

-

RELATED LICENSES

No Related Licenses

SPECIALTY INFORMATION

No Specialty Information

INSPECTION INFORMATION

Inspection Type: Pharmacy Inspection Report

Inspection Date: 5/8/2025

Inspection Grade: Pass

July 22, 2026

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

Re: LillyDirect Pharmacy, LLC
Pharmacy Application

To whom it may concern:

We are writing to provide additional information in support of the pending non-resident pharmacy application for LillyDirect Pharmacy, LLC ("Applicant"), located at 1555 S. Harding St., Ste. 171-B68, Indianapolis, IN 46221, before the Nevada State Board of Pharmacy ("Board").

Specifically, the following statement addresses the affirmative answer to Section 3, Question 3 of the application, which asks "Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?"

The question was answered affirmatively for the following reasons:

1. The Board issued a Citation & Fine, dated March 13, 2026 (case no. 25-402-O), to the Applicant that was not resolved at the time of the application submission. That matter has now been resolved pursuant to the Amended Citation & Fine, dated June 1, 2026, attached hereto; and
2. The Applicant's parent company, Eli Lilly and Company, is a publicly traded corporation that has been in business for over 150 years, and encompasses numerous current and historical subsidiaries, affiliates, and divisions across multiple jurisdictions; as such, it is not possible to generate a complete list.

Please let us know if you have any questions or require additional information.

Sincerely,

Joshua Wheat
Pharmacist-in-Charge
LillyDirect Pharmacy, LLC

Enclosure

JOE LOMBARDO
Governor

STATE OF NEVADA
BOARD OF

HELEN
PARK
President

J. DAVID
WUEST
Executive

[DATE], 2026

Via Certified/Standard U.S. Mail
LillyDirect Pharmacy, LLC
1555 S. Harding Street, Ste 171-B68
Indianapolis, IN 46221

9171 9690 0935 0297 7643 78

Re: AMENDED CITATION & FINE: Case No. 25-402-O, Unlicensed Activity

To Whom It May Concern:

This letter shall supersede the Cease & Desist / Citation & Fine dated March 13, 2026 issued to LillyDirect Pharmacy Solutions.

The Nevada State Board of Pharmacy (Board) reasonably determined that LillyDirect Pharmacy, LLC (LillyDirect Pharmacy) engaged in the practice of pharmacy into the State of Nevada without the required Nevada licensure, in violation of Nevada Revised Statutes (NRS) 639.100, NRS 639.233, and Nevada Administrative Code (NAC) NAC 639.6942.

During an October 2025 investigation of a wellness facility in Reno, the Board discovered that Nevada consumers were obtaining prescription drugs, which are dangerous drugs under Nevada law, facilitated by way of LillyDirect. The Board understands that LillyDirect is a digital healthcare platform that connects patients to third-party telehealth services. Although LillyDirect Pharmacy is a non-dispensing pharmacy, its support activities to LillyDirect still fall within the scope of operations that require a license from the Board. Specifically, an unlicensed seller of prescriptions drugs is deemed to be engaged in the business of furnishing prescription drugs in Nevada if the seller solicits or accepts orders for those drugs from a Nevada purchaser regardless of whether the seller actually ships those products into the state. See NRS 639.233(2)(a); cf. NRS 639.233(2)(b). Further, the practice of pharmacy includes the receipt of prescriptions and other confidential information relating to patients. NRS 639.0124.

Because LillyDirect Pharmacy is not a Nevada licensed pharmacy, manufacturer, or wholesaler, it cannot solicit orders for prescription drugs in Nevada. *See* NRS 639.100(1); NRS 639.233. This letter serves as a **CITATION** pursuant to NRS 639.2895(2). Pursuant to NRS 639.2895(3), the Board has assessed an administrative fine against LillyDirect Pharmacy in the amount of **Five Thousand Dollars ($5,000.00).**

You have the right to appeal this citation by submitting a written request for a hearing to the Board at the Board's Reno office no later than 30 days after receipt of this citation. NRS 639.2895(2). Unless you submit a timely appeal, the above fine must be paid within the same time frame. Payment must be tendered in the form of a certified check, cashier's check or money order made payable to "**State of Nevada, Office of the Treasurer**." Please remit payment to the Board's Reno office, located at 985 Damonte Ranch Parkway — Suite 206, Reno, NV 89521.

If you fail to timely pay the above fine or appeal this citation, as applicable, the Board may take further action, including referral to the Nevada Controller's Office for collection. *See* NRS 353C.195. If you have any questions concerning this citation or your right to appeal the above finding, you may contact the Board's Regulatory Compliance Officer Skylar Young at 775-850-1440, ext. 151, or by email at Skylaryoung@pharmacy.nv.gov.

Sincerely,

The Nevada State Board of Pharmacy

Jonathan A. Keller
Partner
jonathan.keller@faegredrinker.com
Connect: vCard

+1 973 549 7059 direct

Faegre Drinker Biddle & Reath LLP
600 Campus Dr.
Florham Park, New Jersey 07932, USA

From: Keller, Jonathan A. <jonathan.keller@faegredrinker.com>
Sent: Friday, June 19, 2026 4:04 PM
To: skylaryoung@pharmacy.nv.gov
Cc: dwuest@pharmacy.nv.gov
Subject: LillyDirect Pharmacy, LLC Case No. 25-402-O

Dave and Skylar,

Good afternoon. I am writing to provide you with an update on the LillyDirect Pharmacy (Case No. 25-402-0) matter. The attached letter along with payment for the $5,000 administrative fine has been mailed to your office. I was delivered earlier today. Please reach out with any questions. Thank you.

Shipment facts

Shipment overview

TRACKING NUMBER	873255102200
DELIVERED TO	Shipping/Receiving
SHIP DATE	6/18/26
STANDARD TRANSIT	6/19/26 before 12:00 PM
DELIVERED	6/19/2026 at 9:42 am

Jonathan A. Keller
Partner
jonathan.keller@faegredrinker.com
Connect: vCard

+1 973 549 7059 direct

Faegre Drinker Biddle & Reath LLP
600 Campus Dr.
Florham Park, New Jersey 07932, USA

This message and any attachments are for the sole use of the intended recipient(s) and may contain confidential and/or privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message and any attachments.

JOE LOMBARDO
Governor

HELEN PARK
President

J. DAVID WUEST
Executive Secretary

STATE OF NEVADA
BOARD OF PHARMACY

June 1, 2026

Via Certified/Standard U.S. Mail
LillyDirect Pharmacy, LLC
1555 S. Harding Street, Ste 171-B68
Indianapolis, IN 46221

9171 9690 0935 0297 7644 08

Re: AMENDED CITATION & FINE: Case No. 25-402-O, Unlicensed Activity

To Whom It May Concern:

This letter shall supersede the Cease & Desist / Citation & Fine dated March 13, 2026 issued to LillyDirect Pharmacy Solutions.

The Nevada State Board of Pharmacy (Board) reasonably determined that LillyDirect Pharmacy, LLC (LillyDirect Pharmacy) engaged in the practice of pharmacy into the State of Nevada without the required Nevada licensure, in violation of Nevada Revised Statutes (NRS) 639.100, NRS 639.233, and Nevada Administrative Code (NAC) NAC 639.6942.

During an October 2025 investigation of a wellness facility in Reno, the Board discovered that Nevada consumers were obtaining prescription drugs, which are dangerous drugs under Nevada law, facilitated by way of LillyDirect. The Board understands that LillyDirect is a digital healthcare platform that connects patients to third-party telehealth services. Although LillyDirect Pharmacy is a non-dispensing pharmacy, its support activities to LillyDirect still fall within the scope of operations that require a license from the Board. Specifically, an unlicensed seller of prescriptions drugs is deemed to be engaged in the business of furnishing prescription drugs in Nevada if the seller solicits or accepts orders for those drugs from a Nevada purchaser regardless of whether the seller actually ships those products into the state. See NRS 639.233(2)(a); cf. NRS 639.233(2)(b). Further, the practice of pharmacy includes the receipt of prescriptions and other confidential information relating to patients. NRS 639.0124.

Because LillyDirect Pharmacy is not a Nevada licensed pharmacy, manufacturer, or wholesaler, it cannot solicit orders for prescription drugs in Nevada. *See* NRS 639.100(1); NRS 639.233. This letter serves as a **CITATION** pursuant to NRS 639.2895(2). Pursuant to NRS 639.2895(3), the Board has assessed an administrative fine against LillyDirect Pharmacy in the amount of **Five Thousand Dollars ($5,000.00).**

You have the right to appeal this citation by submitting a written request for a hearing to the Board at the Board's Reno office no later than 30 days after receipt of this citation. NRS 639.2895(2). Unless you submit a timely appeal, the above fine must be paid within the same time frame. Payment must be tendered in the form of a certified check, cashier's check or money order made payable to "**State of Nevada, Office of the Treasurer**." Please remit payment to the Board's Reno office, located at 985 Damonte Ranch Parkway — Suite 206, Reno, NV 89521.

If you fail to timely pay the above fine or appeal this citation, as applicable, the Board may take further action, including referral to the Nevada Controller's Office for collection. *See* NRS 353C.195. If you have any questions concerning this citation or your right to appeal the above finding, you may contact the Board's Regulatory Compliance Officer Skylar Young at 775-850-1440, ext. 151, or by email at Skylaryoung@pharmacy.nv.gov.

Sincerely,

The Nevada State Board of Pharmacy

11

11A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

APPLICATION FOR ~~OUT-OF-STATE~~ OUTSOURCING FACILITY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New OUTSOURCING FACILITY
☐ Ownership Change (Provide current license number if making changes:) OUT_____
☐ 503a OR ☒ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4
☒ Non Publicly Traded Corporation – Pages 1-3 & 5
☐ Partnership - Pages 1-3 & 6
☐ Sole Owner – Pages 1-3 & 7

X

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Bespoke Pharmaceuticals, LLC

Physical Address: 5795 N. Hollywood Blvd.

City: Las Vegas State: NV Zip Code: 89115

Telephone: (725) 529-3930 Fax: (725) 529-3572

Toll Free Number: (877) 277-6558 (Required per NAC 639.708)

E-mail: japheth@bespokepharmaceutical.com Website: www.bespokepharmaceutical.com

Supervising Pharmacist: Jaymie Padero Nevada License #: 23846

SERVICES PROVIDED

Yes/No

☒ ☐ Parenteral
☒ ☐ Sterile Compounding
☐ ☒ Non Sterile Compounding
☐ ☒ Mail Service Sterile Compounding
☐ ☒ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: 5/8/26 Amount: cc $500

FEI Number (From FDA application): _____

Please provide the name of the facility as registered with the FDA and the registration number:
Bespoke Pharmaceuticals, LLC

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
Bespoke Pharmaceutical, LLC

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Jaymie Padero Nevada License Number: 23846

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: NV20201930582

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☒

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Fadi Abdel

Print Name of Authorized Person

5.6.2026

Date

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: State of Nevada

Parent Company if any: N/A

Address: 5795 N. Hollywood Blvd.

City: Las Vegas State: NV Zip: 89115

Telephone: (725) 529-3930 Fax: (725) 529-3572

Contact Person: Japheth Noah

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) Rise Equipment, LLC [redacted] Sherman Oaks, CA [redacted] 50.1%
Name Address

b) Pharma X, LLC [redacted] Sunny Isles, FL [redacted] 49.9%
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. N/A - LLC membership interests

3) What was the price paid per share? N/A

4) What date did the corporation actually receive the cash assets? N/A

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

Attachment: Ownership Structure and Officers/Managers

Applicant: Bespoke Pharmaceuticals, LLC
Facility Address: 5795 N. Hollywood Blvd., Las Vegas, NV 89115
Ownership Type: Non Publicly Traded Corporation or Company

Ownership Structure

Owner or Member	TIN	Business Address	Ownership
Rise Equipment, LLC	85-2438627	[redacted] Sherman Oaks, CA [redacted]	50.1%
Pharma X, LLC	85-3924668	[redacted] Sunny Isles, FL [redacted]	49.9%

Officers and Managers

Name	Title	Business Address	Phone	Home Address
Irina Gampel	Manager	5795 N. Hollywood Blvd. North Las Vegas, NV 89115	[redacted]	Sunny Isles Beach, FL [redacted]
Irina Sarafyan	Manager	5795 N. Hollywood Blvd. North Las Vegas, NV 89115	[redacted]	Sherman Oaks, CA [redacted]

Notes for Board Review

* The applicant is an LLC and is being submitted under the Non Publicly Traded Corporation or Company pathway, consistent with the form instruction for LLC applicants.
* The company has two members and does not exceed four shareholders or members.
* No physician shareholders were identified in the ownership information used to prepare this attachment.

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Bespoke Pharmaceuticals, LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 10/30/2020, and in good standing in this State.

I further certify that the above DOMESTIC LIMITED-LIABILITY COMPANY (86) has its formation or qualification document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 03/25/2026.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202603256578901

You may verify this certificate online at https://www.nvsilverflume.gov/home

Drug Establishments Current Registration Site

New Search (index.cfm)

Search Results for **Bespoke Pha**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Bespoke Pharmaceutical, LLC	3032391393	117989075	LABEL; MANUFACTURE; RELABEL; REPACK;	5795 N Hollywood Blvd, Las Vegas, Nevada (NV) 89115-1833, United States (USA)	12/31/2026

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Sunday, Apr 12, 2026

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Registered Outsourcing Facilities

Facilities Registered as Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Updated as of 4/2/2026

- Information Concerning Outsourcing Facility Registration (/drugs/compounding/questions-and-answers-outsourcing-facility-registration)
- Outsourcing Facility Product Reporting Information (/drugs/compounding/information-outsourcing-facilities#reporting)

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

Search: bespoke

Show 10 entries

Export Excel

Facility	Contact	Initial Registration Date [1]	Most Recent Registration Date [1]	Last Inspection [2]	Form 483 Issued? [3]	Recall Conducted? [9]	Action Based on Last Inspection [4,5]	Intends to Compound Sterile Drugs From Bulk Substances [6]
Bespoke Pharmaceutical, LLC, Las Vegas, NV	Japheth Noah 1-857-995-7999	3/7/2026	3/7/2026	Not yet inspected	N/A	N/A	N/A	Yes

Showing 1 to 1 of 1 entries (filtered from 92 total entries)

Previous 1 Next

Feedback

Notes

1. The "initial date of registration as an outsourcing facility" is the date the facility was first registered (i.e., the date FDA determined that the initial registration information submitted for the facility was complete, and the establishment fee was paid in full).

   Under section 503B(b) of the FD&C Act, after the initial registration, a facility that elects to continue to be registered with FDA as an outsourcing facility must re-register annually. A facility that elects to register (or re-register) with FDA as an outsourcing facility must pay an annual establishment fee. The "date of most recent registration as an outsourcing facility" reflects the date FDA determined the most recently submitted registration information was complete and the annual establishment fee for that fiscal year paid in full.

   Unless a previously registered outsourcing facility re-registers and pays the annual establishment fee in full during the registration period (between October 1 and December 31 of each calendar year), the facility will be removed from the list of registered outsourcing facilities on January 1 of the next calendar year.

2. Once an outsourcing facility is registered, the facility will be added to the list of facilities FDA intends to inspect according to a risk-based schedule. FDA plans to inspect outsourcing facilities within a reasonable period of time following initial registration, once it is confirmed that the facility has initiated drug production and distribution. However, the exact timing of the inspections can be affected by a number of variables, including the number of outsourcing facility registrants, other inspection priorities, and the operational status of the newly registered outsourcing facility.

   Inspections identified in this table are associated with the facility at the listed address. A company may own or operate more than one registered outsourcing facility. FDA's web page Compounding: Inspections, Recalls, and other Actions (/node/363232) may contain information about compounding facilities under the same ownership as the listed registered outsourcing facility.

   Inspections may take place over several days, weeks or longer. The date of the inspection is the date a Form FDA 483 listing the investigators' observations was issued. If no FDA Form 483 was issued, the date is the last day of the inspection.

3. A Form FDA 483 is issued when investigators observe any significant objectionable conditions. It does not constitute a final agency determination of whether any condition is in violation of the FD&C Act or any relevant regulations.

4. This table does not include State Board of Pharmacy actions, if any. To determine whether a registered outsourcing facility has been the subject of a state enforcement action, check with the State Board of Pharmacy for the state in which the facility is located. Some states post disciplinary or other actions on their web sites.
5. "Closed" means the inspection has been closed without further action. "Open" means FDA has not determined whether further action will be taken. If an action has been taken, it will be listed. Possible FDA actions include warning letter, seizure or injunction.
6. The information in this column was provided by the registered outsourcing facility at the time of registration and has not been verified by FDA. "N/A" indicates the registered outsourcing facility has not provided this information.
7. This outsourcing facility was the subject of at least one previous inspection relating to compounding that resulted in a Form FDA 483, warning letter or other action. For information about such inspections and resulting actions, visit Compounding: Inspections, Recalls, and other Actions (/node/363232).
8. A remote regulatory assessment (RRA) is an examination of an FDA-regulated establishment and/or its records, conducted remotely, to evaluate compliance with applicable FDA requirements. These assessments assist in protecting human and animal health, inform regulatory decisions and verify certain information submitted to the agency.
9. Based on inspectional findings, the inspection revealed significant issues. As a result, the outsourcing facility may have either initiated a recall on their own following conversation(s) with the FDA investigator or FDA recommended a recall at the conclusion of the inspection or both. Additionally, the outsourcing facility may have conducted multiple recalls or recalled multiple drugs.

Was this page helpful? * (required)

Yes

No

Submit

An official form of the United States government. Provided by Touchpoints

NEVADA STATE BOARD OF PHARMACY

98S Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Bespoke Pharmaceuticals, LLC

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 5795 N Hollywood Blvd

City: Las Vegas State: NV Zip: 89115

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 725 529 3930 Toll Free # (NAC 639.708, NRS 639.23286): 877 277 6558

Fax: 725 529 3572 Contact Email: japheth@bespokepharmaceutical.com

Website: www.bespokepharmaceutical.com

Nevada Business License # (if applicable) NV20201930582

Supervising/Managing Pharmacist Name (NRS 639.220): Jaymie Padero

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23846

Name of Designated Person(s) as defined by revised USP-797 guidelines: Japheth Noah

Email of Designated Person(s): japheth@bespokepharmaceutical.com

Telephone of Designated Person(s): 857 995 7999

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ☐ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☐ Yes ■ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☐ Aseptic ■ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? February 2026

6. What is the frequency of the recertification for the ISO classified areas? Annually

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Per environmental monitoring schedule & after significant events, maintenance, & excursion

10. Will you be performing sterile hazardous drug compounding? Yes ■ No

If you marked **"Yes"**, you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Sterile compounded preparations containing methylcobalamin, sermorelin, NAD+, glutathione, and gonadorelin.

12. What laboratory performs your sterility or endotoxin testing?

Name: Nelson Laboratories, LLC

Address: 6280 S. Redwood Road

City: Salt Lake City State: UT Zip: 84123

Telephone: 801 290 7625

13. What is your procedure for visual inspection of compounded sterile products?
Each finished compounded sterile product is visually inspected by trained and qualified personnel using manual, semi automated, or automated inspection, as applicable, before release. Inspection includes solution clarity, color, visible particulate matter, container closure integrity, fill volume, stopper and seal integrity, cracks, leaks, cosmetic defects, and labeling accuracy, including lot identification and beyond use date or expiry information. Any unit that does not meet acceptance criteria is rejected and investigated in accordance with written procedures.

14. How often do you perform glove fingertip and medial fill testing?
Glove fingertip and thumb sampling and media fill qualification are completed initially, requalified per procedure, and repeated after failures, major changes, extended absence, or retraining.

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
All personnel involved in sterile compounding complete initial training before performing any sterile compounding duties independently and complete ongoing requalification thereafter. Training includes personnel hygiene and garbing, aseptic technique, cleanroom behavior, material staging and transfer, equipment operation, environmental monitoring awareness, cleaning and disinfection practices, batch record documentation, deviation reporting, visual inspection, labeling controls, and applicable requirements under USP 797 and the facility quality system. Personnel must successfully complete required practical and written qualification activities, including gowning qualification, glove fingertip and thumb sampling, media fill qualification, and role specific competency assessments.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
Primary and secondary engineering controls are cleaned and disinfected in accordance with written procedures and established schedules. Cleaning is performed using qualified cleaning and disinfecting agents before operations begin, at defined intervals during operations as applicable, after compounding is completed, and after any spill, contamination event, or maintenance activity requiring additional cleaning. Disinfecting and sporicidal agents are used at defined routine frequencies under the environmental cleaning program. All cleaning activities are documented in facility logs and reviewed under the quality system. The specific agents used are listed below and are as approved in current procedures: Different types of Liquidnox cleaning agents, isopropyl alcohol (70%) Ready to use (RTU) Peridox, Tex Q, Sporkenz and ionized hydrogen peroxide.

17. Who performs the sterile compounding process at your facility?

Licensed pharmacists and certified pharm. techs perform sterile compounding after training, qualification, & authorization.

18. Who is responsible and accountable for the sterile compounding process at your facility?
Responsibility for sterile compounding rests with the supervising pharmacist, designated person under USP 797, and Quality Assurance, including oversight of personnel qualification, environmental monitoring, deviations, cleaning, disinfection, and procedural compliance.

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
Products are shipped under labeled storage conditions using qualified packaging, temperature controls, and cold chain packaging and temperature monitoring devices when required. Shipping conditions are documented and reviewed, and any temperature excursion is assessed under written procedures before product disposition.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility?		
2. Are you complying with all USP 800 guidelines?	Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	No
5. Do you have a negative pressure buffer room at your facility?	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?

5. What is the frequency for completing surface sampling?		
6. What is the frequency for using sporicidal agents?		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Japheth Noah

Name of Person who Completed the Form

Head of Quality Assurance, Quality Control, and Development

Title

JNoah

Signature (copies or stamps not accepted)

06/03/2026

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Bespoke Pharmaceuticals, LLC

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 5795 N Hollywood Blvd

City Las Vegas State NV Zip 89115

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (725) 529-3930 Website www.bespokepharmaceutical.com

Licensing Company Email license@bespokepharmaceutical.com

Section 2: Personal Information

First Japheth Middle _____ Last Noah

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Oxford		07/83 -07/85	
Address	**City**	**State**	**Zip**
Wellington Square	Oxford	UK	Ox1 2JD
Diploma/Degree obtained, if any			
MSc Physical Sciences			

School Name		From - To (MM/YY – MM/YY)	
Alexandria University		04/78 - 09/82	
Address	**City**	**State**	**Zip**
22 El-Guish Road, El-Shatby	Alexandria	Egypt	21526
Diploma/Degree obtained, if any			
Bachelor's of Science			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/24 - present	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Bespoke Pharmaceuticals, LLC			02/24- present
Business Address	**City**	**State**	**Zip**
5795 N Hollywood Blvd	Las Vegas	NV	89115
Phone	**Title**	**Number of Employed Hours**	
(725) 529-3930	Head of QA/QC and Development	5,050 hours	
Description of Duties			
Executive responsible for everything from leading quality assurance, quality control, regulatory affairs, manufacturing, validation, testing and product development.			

Business Name			From - To (MM/YY – MM/YY)
Shalby Advance Technologies, Inc.			11/22 - 02/24
Business Address	**City**	**State**	**Zip**
1115 Windfield Way	El Dorado Hills	CA	95762
Phone	**Title**	**Number of Employed Hours**	
(844) 228-2366	Vice President of Quality Assurance and Regulatory Affairs	6,240 hours	
Description of Duties			
Directed global quality assurance and regulatory affairs operations across pharmaceutical and medical device portfolios			

Business Name			From - To (MM/YY – MM/YY)
Andelyn Biosciences			04/21 - 11/22
Business Address	**City**	**State**	**Zip**
1180 Arthur E. Adams Drive	Columbus	OH	43221
Phone	**Title**	**Number of Employed Hours**	
(650) 200-0412	Associate Director and Head of Quality Assurance	2,080 hours	
Description of Duties			
Directed quality assurance systems and compliance activities within a global CDMO setting and supported quality assurance and quality control.			

Business Name			From - To (MM/YY – MM/YY)
Sharp Sterile Manufacturing			09/20 - 04/21
Business Address	**City**	**State**	**Zip**
480 Pleasant Street	Lee	MA	01238
Phone	**Title**	**Number of Employed Hours**	
(413) 243-0330	Senior Systems & Compliance Manager	2,080 hours	
Description of Duties			
Oversaw quality assurance for biologics and advanced therapy manufacturing within a CDMO environment, leading client			

Business Name			From - To (MM/YY – MM/YY)
Intertek Pharmaceutical Services			07/19 - 09/21
Business Address	**City**	**State**	**Zip**
291 Route 22 East	Whitehouse	NJ	08888
Phone	**Title**	**Number of Employed Hours**	
(800) 967-5352	Global Auditor & Reviewer	6,240 hours	
Description of Duties			
Conducted audits across the United States, Europe, Canada, Asia, and Africa, with focus on GMP, ISO, and medical device			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Japheth Noah, **certify that as the designated representative for**

Bespoke Pharmaceutical,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JN I am at least 21 years of age;
3. JN I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JN I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JN I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JN I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JN I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Japheth Noah

Print Name (First, Last)

JNoah

Original Signature (electronic, copies or stamps not accepted)

06/03/2026

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JAPHETH NOAH

Print Name (First, Last)

JNaeNoah

Original Signature (electronic, copies or stamps not accepted)

06/03/2026

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Japheth Wandu Noah, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

JNaeNoah

Original Signature

06/03/2026

Date

Subscribed and Sworn to before me this 3rd day of June 2026.

LDemmel

Notary Public Signature

LISA DEMMEL
Notary Public, State of Nevada
No. 20-3203-01
My Appt. Exp. Dec. 30, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site BESPOKE PHARAMCEUTICALS, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 5795 N. HOLLYWOOD BLVD

City NORTH LAS VEGAS State NV Zip 89115

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 877 277 6558 Website BESPOKEPHARMACEUTICAL.COM

Licensing Company Email LICENSE@BESPOKEPHARAMCEUTICAL.COM

Section 2: Personal Information

First IRINA Middle _____ Last GAMPEL

Alias(es, nicknames, name changes, etc.) BARSKI, MOSCOWITZ

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City SUNNY ISLES BEACH State FL Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
SAN DIEGO STATE UNIVERSITY			09/95 - 05/99
Address	**City**	**State**	**Zip**
5500 CAMPANILE DR	SAN DIEGO	CA	92182
Diploma/Degree obtained, if any			
BS OF SCIENCE MANAGEMENT			

School Name			From - To (MM/YY – MM/YY)
RESEDA HIGH SCHOOL			09/92 - 05/95
Address	**City**	**State**	**Zip**
18230 KITTRIDGE ST	RESEDA	CA	91335
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/20 - PRESENT	[redacted]	SUNNY ISLES BEACH	FL	[redacted]
08/12 - 07/20		GLENDALE	AZ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
NORTHERN LIGHT MEDICAL MANAGEMENT, LLC			05/23 - PRESENT
Business Address	**City**	**State**	**Zip**
1895 TYLER ST # 207	HOLLYWOOD	FL	33020
Phone	**Title**		
754 900 5014	ACCOUNT MANAGER		
Description of Duties			
DAILY OPERATIONS, OVERSEEING ACCOUNTING AND BANKING			

Business Name			From - To (MM/YY – MM/YY)
ACE MANAGEMENT, LLC			05/19 - PRESENT
Business Address	**City**	**State**	**Zip**
18555 COLLINS AVE #5003	SUNNY ISLES BEACH	FL	33160
Phone	**Title**		
818 697 2977	MANAGING MEMBER		
Description of Duties			
MANAGING MEMBER FOR INVESTMENT AND HOLDING COMPANY; DAILY OPEARATIONS, ACCOUNTING OVERVIEW.			

Business Name			From - To (MM/YY – MM/YY)
NOBILITY MANAGEMENT, LLC			02/15 - 08/22
Business Address	**City**	**State**	**Zip**
26025 MUREAU RD SUITE 110	CALABASAS	CA	91302
Phone	**Title**		
	ACCOUNT MANAGER		
Description of Duties			
OVERSEEING ACCOUNTING, BILLING PROCEDURE IMPLEMENTATION			

Business Name			From - To (MM/YY – MM/YY)
IG INVESTMENTS, INC			04/05 - 09/23
Business Address	**City**	**State**	**Zip**
18555 COLLINS AVE #5003	SUNNY ISLES BEACH	FL	33160
Phone	**Title**		
	SHAREHOLDER		
Description of Duties			
OVERSEEING INVESTMENT PORTFOLIO			

Business Name			From - To (MM/YY – MM/YY)
EMBRACE FOUNDATION, CHARITABLE FOUNDATION			05/18 - PRESENT
Business Address	**City**	**State**	**Zip**
18555 COLLINS AVE #5003	SUNNY ISLES BEACH	FL	33160
Phone	**Title**		
818 697 2977	PRESIDENT		
Description of Duties			
MANAGING ENTITY STRATEGY, CHARITY EVENTS, MANAGING VARIOUS CHANELS FOR CHARITY ACTIVITY.			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
PHARMA X, LLC			10/20 - PRESENT
Business Address	**City**	**State**	**Zip**
18555 COLLINS AVE #5003	SUNNY ISLES BEACH	FL	33160
Phone	**Title**		
818 697 2977	MANAGER		
Description of Duties			
OVERSEES INVESTEMENT *this entity is the member of BESPOKE PHARMACEUTICALS, LLC			

Business Name			From - To (MM/YY – MM/YY)
BESPOKE PHARMACEUTICALS, LLC			10/20 - PRESENT
Business Address	**City**	**State**	**Zip**
5795 N. HOLLYWOOD BLVD	NORTH LAS VEGAS	NV	89115
Phone	**Title**		
877 277 6558	MANAGER		
Description of Duties			
BOARD MEMBER			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

IRINA GAMPEL

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/30/2026

Date

Please have this section completed in the presence of a Notary Public.

State of CALIFORNIA, ss. County of LOS ANGELES

I, Irina Gampel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/30/2026

Date

Subscribed and Sworn to before me this 30TH day of MARCH, 2026.

Notary Public Signature

TREY F. LAFFERTY
Notary Public - California
Los Angeles County
Commission # 2506348
My Comm. Expires Dec 8, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site BESPOKE PHARMACEUTICALS, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 5795 N. HOLLYWOOD BLVD

City NORTH LAS VEGAS State NV Zip 89115

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 877 277 6558 Website BESPOKEPHARMACEUTICAL.COM

Licensing Company Email LICENSE@BESPOKEPHARMACEUTICAL.COM

Section 2: Personal Information

First IRINA Middle _____ Last SARAFYAN

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City SHERMAN OAKS State CA Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
YEREVAN STATE MEDICAL UNIVERSITY			09/91 - 05/96
Address	**City**	**State**	**Zip**
2 KORYUN ST	YEREVAN	ARMENIA	
Diploma/Degree obtained, if any			
DOCTOR OF STOMATOLOGY			

School Name			From - To (MM/YY – MM/YY)
#8 SCHOOL NAMED AFTRER A.S. PUSHKIN			09/81 - 05/91
Address	**City**	**State**	**Zip**
17 MOSKOVYAN ST	YEREVAN	ARMENIA	
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/22 - PRESENT	[redacted]	SHERMAN OAKS	CA	[redacted]
08/01 - 03/22	[redacted]	BURBANK	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
AMERIDENT HEALTH PRO, INC			09/18 - PRESENT	
Business Address	**City**	**State**	**Zip**	
310 S SEPULVEDA BLVD	LOS ANGELES	CA	90034	
Phone	**Title**			
310 268 0646	PRESIDENT			
Description of Duties				
EXECUTIVE/OVERSEEING DAILY OPERATIONS				

Business Name			From - To (MM/YY – MM/YY)	
SARAFYAN DENTAL PROFESSIONAL CORPORATION			05/15 - PRESENT	
Business Address	**City**	**State**	**Zip**	
3130 S SEPULVEDA BLVD	LOS ANGELES	CA	90034	
Phone	**Title**			
310 767 6199	PRESIDENT			
Description of Duties				
DENTIST (LICENSED ONLY IN STATE OF CALIFORNIA. CA LICENSE NUMBER 57323)				

Business Name			From - To (MM/YY – MM/YY)	
ANSALIGY USA, LLC			07/19 - 09/22	
Business Address	**City**	**State**	**Zip**	
16850 COLLINS AVE # 113	SUNNY ISLES BEACH	FL	33160	
Phone	**Title**			
305 903 2226	PRESIDENT			
Description of Duties				
EXECUTIVE/ESTABLISHED PROTOCOLS AND PROCEDURES FOR THE BEAUTY PRODUCT LINE DISTRIBUTION COMPANY.				

Business Name			From - To (MM/YY – MM/YY)	
RISE EQUIPMENT, LLC			08/20 - PRESENT	
Business Address	**City**	**State**	**Zip**	
3679 BENEDICT CANYON LANE	SHERMAN OAKS	CA	91423	
Phone	**Title**			
310 767 6199	VICE PRESIDENT			
Description of Duties				
EXECUTIVE *this entity is the member of BESPOKE PHARMACEUTICALS, LLC				

Business Name			From - To (MM/YY – MM/YY)	
BESPOKE PHARMACEUTICALS, LLC			10/20 - PRESENT	
Business Address	**City**	**State**	**Zip**	
5795 N. HOLLYWOOD BLVD	NORTH LAS VEGAS	NV	89115	
Phone	**Title**			
877 277 6558	MANAGER			
Description of Duties				
BOARD MEMBER				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

IRINA SARAFYAN

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/31/2026

Date

Please have this section completed in the presence of a Notary Public.

State of CALIFORNIA, ss. County of LOS ANGELES

I, IRINA SARAFYAN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

03/31/2026

Date

Subscribed and Sworn to before me this 31st day of March 2026.

Notary Public Signature

Please see attached certificate for notary.

(Seal)

CALIFORNIA JURAT **GOVERNMENT CODE § 8202**

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Los Angeles

Subscribed and sworn to (or affirmed) before me on this 31st day of March, 20 26, by

(1) Irina Sarafyan

(and (2) _____),

Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

ARASH REZAEE-TARI
Notary Public - California
Los Angeles County
Commission # 2534939
My Comm. Expires Oct 10, 2029

Place Notary Seal and/or Stamp Above

Signature _____

Signature of Notary Public

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Nevada State Board of Pharmacy Personal History Application

Document Date: _____ Number of Pages: _____

Signer(s) Other Than Named Above: _____

©2018 National Notary Association

Candy Nally

From: License <license@bespokepharmaceutical.com>
Sent: Friday, September 4, 2026 10:13 AM
To: David Wuest
Cc: Candy Nally; Mark I. Sedar; James Gaines; Magdalena Cybulska; Khoi Vu
Subject: Bespoke Pharmaceutical – Corrective Actions and Follow-Up Following NVBP Hearing
Attachments: NVHA Permit_CL-039-38398_expires 2027.pdf

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Good morning Dave,

Thank you again for taking the time to speak with me yesterday afternoon following the NVBP hearing regarding Bespoke's Outsourcing Facility application. I genuinely appreciate your willingness to have the conversation with me and, more importantly, for providing candid feedback and perspective regarding the concerns raised by the Board and legal counsel. Our conversation was extremely helpful, and I want you to know that I take the Board's feedback very seriously. I also now understand that there was a miscommunication regarding the expectation that ownership be present at the hearing. I regret that we did not have that understanding beforehand. I had made several attempts to connect prior to the meeting, but regardless, I completely understand the Board's perspective and concern and appreciate you taking the time to explain it to me directly. I view our conversation as an important opportunity to make sure we are fully aligned going forward.

Following our discussion, I wanted to personally confirm that we have already taken action on each of the concerns you brought to my attention.

1. Website and Product Advertising

We immediately reviewed our website and external communications to ensure that nothing could be interpreted as representing that Bespoke is currently an approved or operational 503B outsourcing facility. Effective September 3, 2026, we removed all product advertising and product profiles that could potentially suggest that these products are currently available for commercial manufacture or distribution. We have also instructed our team to review all social-media communications and ensure that nothing could imply that Bespoke currently has approval to operate as an outsourcing facility or to manufacture and distribute 503B products. Going forward, we will be extremely careful to clearly distinguish between our future intended capabilities and activities for which we have actually received regulatory authorization. We are also implementing employee retraining to ensure that our entire team understands the importance of this distinction and that this issue does not recur.

2. Incorrect Representation of My Professional Credentials

Thank you for bringing this up to my attention. We immediately addressed the concern regarding the inaccurate public representation of my professional credentials in connection with my roles as Chief of Development & Operations Officer and Designated Representative. I want to assure you that the reference to me as a Medical Doctor was not deliberate or an attempt to misrepresent my qualifications. It was an inadvertent oversight by our IT/content-development team. Nevertheless, we recognize the importance of ensuring that all professional titles, credentials, biographies, and representations are completely accurate. Upon becoming aware of the issue, I immediately directed our team to remove and correct the inaccurate information. Our staff and IT/content-development personnel have also been retrained regarding the importance of accurately representing professional credentials. As an additional preventive measure, we are implementing an enhanced internal review process for all professional titles, credentials, biographies, and regulatory representations before anything is published externally. Bespoke also maintains formal employment and credential-verification procedures through our HR platform, including E-Verify, and our personnel are verified and appropriately qualified as part of our onboarding process. We take the accuracy and integrity of our personnel records very seriously.

3. Pharmacist-in-Charge and 503B Experience

I appreciate the Board's concern regarding the lack of direct 503B experience in our current Pharmacist-in-Charge, and while we believe Magdalena Cybulska's qualifications are substantial, we are taking the concern seriously and proactively addressing it.

Our review of the applicable Nevada and federal regulatory framework indicates that there is not a specific Nevada requirement establishing a minimum number of years of prior 503B experience for a Pharmacist-in-Charge. We understand, however, that the Board has legitimate concerns regarding the experience necessary to appropriately oversee an outsourcing-facility operation. Magdalena is an actively licensed pharmacist and certified GxP professional with more than five years of compounding experience, extensive knowledge of pharmacology and peptide-related development, and a professional record without revocation or disciplinary concerns. She has been practicing since 2016 and has substantial education, training, and practical experience relevant to the responsibilities assigned to her. Nevertheless, we have decided to proactively mitigate the concern by expanding our pharmacy leadership resources. We have instructed our HR leadership to begin recruiting a Nevada-licensed pharmacist with direct 503B experience who could either supplement Magdalena's responsibilities or, if ultimately determined to be more appropriate for the application and the Board's expectations, assume an expanded leadership role. If the Board or anyone associated with the Board is aware of a qualified pharmacist with 503B experience who may be interested in relocating to Las Vegas and becoming part of the Bespoke ONE team, we would sincerely appreciate any referral or introduction. Please also be reminded that we have identified Khoi Vu as a qualified backup pharmacist. Khoi has served as a Pharmacist-in-Charge in Nevada for many years and, to our understanding, has previously been inspected by the Nevada Board of Pharmacy while serving in that capacity without findings. In addition, Bespoke has established a qualified and trained Quality Control Unit with responsibility for our quality systems and appropriate quality oversight. Our objective is to have multiple layers of qualified personnel, pharmacy leadership, and quality oversight rather than relying upon any single individual. Furthermore, we are having Magdalena and Khoi complete their specialized post-licensure credentials, primarily centered around USP <797> and <800> and ASHP compounded sterile preparation certification with the BCSCP and/or ACPE pharmacy program. Please also note that all staff members are GMP, GDP, and Good pharmacovigilance program trained and certified. Our quality control unit is/will be GLP trained and certified.

4. API, Former 503A Inventory, Manufacturing Authorization, and R&D Activities

Bespoke acknowledges that its former Nevada pharmacy license, under which it conducted 503A compounding activities, has been surrendered, that all 503A compounding and dispensing activities have ceased, and that Bespoke does not rely on that former pharmacy license as authority for any current activity; accordingly, any API or excipients remaining from the former pharmacy operation have been segregated and placed under controlled status pending confirmation of their appropriate disposition or lawful transfer under Bespoke's separate, currently effective authorizations. At the same time, we respectfully believe it is important to distinguish the surrendered pharmacy authority from Bespoke's separate Nevada drug-manufacturing authority (attached) and from the lawful procurement and possession of components for bona fide laboratory research and development. Bespoke currently holds Nevada Health Authority credential CL-039-38398 as a "DRUG" establishment, with no restriction listed on the credential, although we recognize that this authorization does not itself authorize premature 503B outsourcing-facility production. Nevada's drug-manufacturing regulations expressly contemplate a licensed manufacturer's receipt and possession of components: NAC 585.380 requires that, "upon receipt," a licensee safely and orderly store and handle components, prevent cross-contamination, and withhold those components from use until they have been identified, sampled, tested against specifications, and approved by the quality control unit; NAC 585.410 further requires records of the component identity and quantity, supplier, supplier lot number, date of receipt, testing, rejection and disposition. In addition, NRS 454.316(2) expressly provides that a prescription is not required for possession of dangerous drugs by manufacturers or laboratories authorized by Nevada law to handle, possess and deal in such drugs when maintained in properly labeled stock containers and procured from a manufacturer, wholesaler or pharmacy. We likewise recognize that NRS 639.100 requires a person engaging in manufacturing, wholesale distribution, compounding, sale or dispensing to hold the appropriate license or permit and comply with Board regulations, and Bespoke is not interpreting its existing manufacturer authorization as permission to conduct 503B production, dispensing or commercial distribution while the Outsourcing Facility application remains pending. Accordingly, our understanding is that the surrender of Bespoke's former pharmacy license does not, by itself, establish a categorical prohibition against Bespoke, acting under its separate lawful manufacturer framework, procuring and possessing appropriately sourced API solely for controlled research and development purposes only, including but not limited to, analytical method development, characterization, laboratory research and other permitted development activities that are not used for unauthorized 503B production, dispensing, distribution, sale or human administration. To ensure complete alignment with the Board, we respectfully request confirmation of this distinction and, if the Board interprets any provision of NRS Chapters 454, 585 or 639, or NAC Chapters 585 or 639, as prohibiting such procurement

or possession while Bespoke's Outsourcing Facility application remains pending, we respectfully request identification of the specific statutory or regulatory provision so that we may immediately incorporate that requirement into our procedures and controls.

5. Facility Inspection and Invitation to the Board

We appreciated the previous inspection and tour of our facility by the NVBP inspector, including the review conducted during the surrender of our 503A license. At the same time, we recognize that transparency and continued access are extremely important as we move through the 503B application process. For that reason, I would like to formally extend an open invitation to you, General Counsel, members of the Nevada Board of Pharmacy, and appropriate Board staff to visit Bespoke at any time that is convenient for the Board. We would welcome the opportunity to personally walk the Board through our facility, infrastructure, controlled areas, SOPs, quality systems, training programs, personnel qualifications, environmental controls, documentation systems, and overall operating practices. Most importantly, we would welcome the opportunity for the Board to meet our ownership and our team directly. We believe that seeing our facility, our people, and our systems firsthand will provide a meaningful opportunity for the Board to see the level of investment, commitment, preparation, and quality culture that has gone into Bespoke. Our doors are open, and we would be pleased to accommodate the Board whenever it believes a visit would be helpful.

6. Clarification of Sterilization Terminology

We also reviewed the language in our Outsourcing Facility application referring to "terminal sterilization." We acknowledge that this terminology was not accurate and want the Board to please make note of that prior to the next hearing. I reviewed the documentation once more to ensure credentials, qualification and information was accurate. Upon my review, I noted that 'terminal sterilization' was marked. Bespoke is not a gamma-irradiation or radiation-sterilization facility and does not represent that we perform terminal sterilization of our finished products. Our intended sterile manufacturing process is based upon validated aseptic processing, which may include, as applicable to the specific product and process, sterilizing filtration, sterilization and depyrogenation of components and containers/closures, aseptic assembly and filling, aseptic closing, and appropriate environmental and process controls. Please let me know if I should correct the application and all supporting documentation so that our sterilization and aseptic-processing capabilities are described accurately and without ambiguity.

Our Commitment to the Board

Dave, I want to personally thank you again for the conversation yesterday. I recognize that the Nevada Board of Pharmacy has an important responsibility to protect patients and ensure that any outsourcing facility operating in Nevada meets the highest standards of safety, quality, integrity, and regulatory compliance. We share that objective completely. Our goal is not simply to obtain a 503B license. Our goal is to build what we believe can become one of the strongest, safest, and most professionally operated outsourcing facilities in the State of Nevada. We want Bespoke to be an organization that the Board can have confidence in and that Nevada can be proud to have within its healthcare ecosystem.

We also see tremendous opportunities to collaborate with the institutions and organizations surrounding our facility, including Roseman University, UNLV, the College of Southern Nevada, Touro University Nevada, and the Las Vegas Chamber of Commerce. We hope to develop partnerships that support education, workforce development, innovation, research, and ultimately better access to high-quality compounded medications for Nevada patients and healthcare providers. Most importantly, I want you to know that I am personally committed to addressing every concern that is brought to my attention. If there is anything else that you, General Counsel, the inspectors, or any member of the Board have identified—whether large or small—I would sincerely appreciate knowing about it as early as possible. My preference is to understand the concern, correct it immediately, document the corrective action, and demonstrate that correction to the Board before the next hearing rather than allow an issue to remain unresolved or misunderstood.

I genuinely appreciate your willingness to provide us with this feedback and guidance. Your support and candor are extremely valuable to me, and I hope our actions demonstrate that we are listening carefully and responding accordingly. I would be honored if you or any of the board can come to our facility and tour it. Please extend the invite to all from the NVBP. Thank you again for your time, your guidance, and your support of Bespoke. We look forward to continuing our collaboration with the NVBP and to earning the Board's confidence through our actions, transparency, and commitment to compliance.

Please do not hesitate to reach out to me directly if there is anything further you would like us to address before the next hearing. We will act promptly.
With sincere appreciation,



FADI ABDEL
CHIEF DEVELOPMENT & OPERATIONS OFFICER

(609) 310-0860

fadi@bespokepharmaceutical.com
www.bespokepharmaceutical.com

5795 North Hollywood Blvd
Las Vegas, NV, 89115

Bespoke
PHARMACEUTICAL

NEVADA HEALTH AUTHORITY

9850 DOUBLE R BLVD, STE 200
RENO, NEVADA 89521
OFFICIAL PERMIT **Permit No.** CL-039-38398

BESPOKE PHARMACEUTICAL LLC **Operator of** BESPOKE PHARMACEUTICAL LLC

at 5795 NORTH HOLLYWOOD BLVD., NORTH LAS VEGAS, NV 89115

is granted a permit to operate the following

Permit Description: DRUG (W/O AMYGDALIN/PROCAINE HYDROCHLORIDE)

Conditions of Permit: No restrictions

This establishment when inspected did comply with the public health laws of Nevada, and the rules, regulations and codes of Nevada Health Authority in effect on this date.

THIS PERMIT IS NOT TRANSFERABLE AND MUST BE POSTED IN VIEW OF THE PUBLIC.

It is subject to revocation at any time this establishment is not maintained or is not operated in a sanitary manner, and in accordance with Nevada statutes, and with rules, regulations and codes of the Nevada Health Authority. This permit becomes null and void upon the expiration date.

Expiration Date: 06/30/2027 **Official:** Vincent Valiente REHS

(NSPO Rev. 3-14) (O) 1557B

12

12A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☐ Ownership Change* ■ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 02295	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Nephron SC, LLC dba Nephron Pharmaceuticals

Physical Address: 4500 12th Street Extension

City: West Columbia State: SC Zip: 29172

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (800) 443-4313 2829 Website: https://nephronpharm.com

Name of Designated Representative (DR): Lou Wood Kennedy, President and Chief Executive Officer

Licensing Company Email: license@nephronpharm.com DR Email: license@nephronpharm.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Rx OTC drugs	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Fisher Scientific Company
Address: 300 Industry Drive City: Pittsburg State: PA Zip: 15275

Name: ProAm Pac
Address: 165 Chicago Street City: Cary State: IL Zip: 60013

Name: Supply One
Address: 1360 Old Georgia Road City: Roebuck State: SC Zip: 29376

Name: WestRock Mebane
Address: 7411 Oakwood Street Extension City: Mebane State: NC Zip: 27302

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nephron SC, LLC dba Nephron Pharmaceuticals
Parent Company (if any): Nephron, LLC
Corporation/Organization Name: Nephron SC, LLC dba Nephron Pharmaceuticals
Mailing Address: 4500 12th Street Extension
City: West Columbia State: SC Zip: 29172
Telephone: (800) 443-4313 x2829 Email: license@nephronpharm.com
Contact Person Name: Lou Wood Kennedy, President and Chief Executive Officer

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✔	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Nephron SC, LLC dba Nephron Pharmaceuticals

Facility Name

Lou Wood Kennedy, President and Chief Executive Officer

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

01/27/2026

Date

Board Use Only	Date Received: 2/9/26	Amount: $1000-ck 91523

NABP ACCREDITED
DRUG DISTRIBUTOR

Nephron SC, LLC
dba Nephron Pharmaceuticals

located at

4500 12th Street Ext, West Columbia, SC 29172

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

Drug Establishments Current Registration Site

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Nephron SC, LLC	3010892830	079160190	ANALYSIS; LABEL; MANUFACTURE; PACK	4500 12th Street Extension, West Columbia, South Carolina (SC) 29172, United States (USA)	12/31/2025

COPY

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

Drug Establishments Current Registration Site

New Search (index.cfm)

Search Results for **Nephron SC**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Nephron SC, LLC	3010892830	079160190	ANALYSIS; LABEL; MANUFACTURE; PACK;	4500 12th Street Extension, West Columbia, South Carolina (SC) 29172, United States (USA)	12/31/2026

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Thursday, Dec 4, 2025

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Company: Nephron SC, LLC
DBA: Nephron Pharmaceuticals
State of Incorporation: South Carolina
Corporate Address: 4500 12th Street Extension
West Columbia, SC 29172
Parent Company: Nephron, LLC

Corporate Officers

Name	Title	Residential Address	Business Address
Lou Wood Kennedy [redacted]	CEO/President	[redacted]	4500 12th Street Extension West Columbia, SC 29172 (407) 491-9755
Joseph George Mergo, III [redacted]	COO/Vice President/Secretary/Treasurer		4500 12th Street Extension West Columbia, SC 29172 (803) 518-1981

Tax-ID: 45-3731316
FEI Number: 3010892830



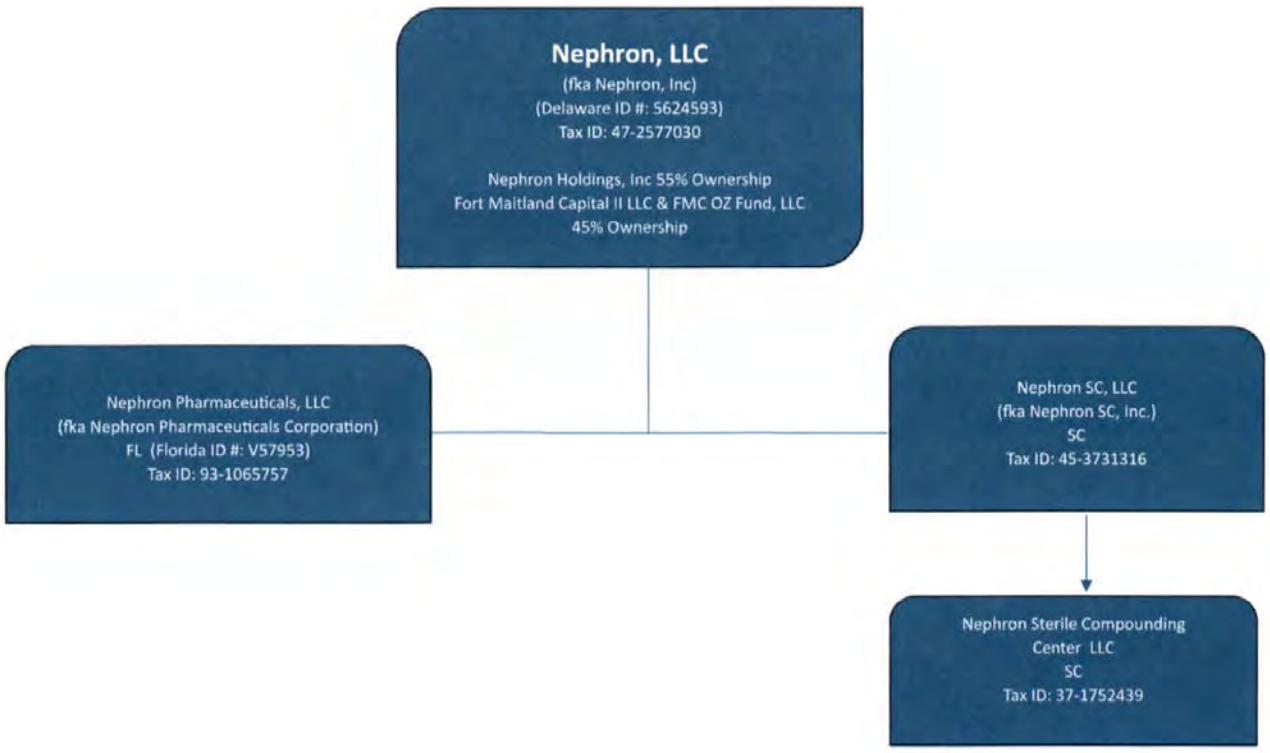
Company: Nephron SC, LLC
DBA: Nephron Pharmaceuticals
State of Incorporation: South Carolina
Corporate Address: 4500 12th Street Extension
West Columbia, SC 29172
Parent Company: Nephron, LLC

Owners

Name	Percentage Interest	Business Address
Nephron, LLC	100%	Attn: Mrs. Lou W. Kennedy, President & CEO 4500 12th Street Extension West Columbia, SC 29172
Totals:	100%	

nephron
pharmaceuticals corporation

Corporate Structure



The State of South Carolina

Office of Secretary of State Mark Hammond

Certificate of Existence

I, Mark Hammond, Secretary of State of South Carolina Hereby Certify that:

NEPHRON SC, LLC, a limited liability company duly organized under the laws of the State of South Carolina on November 4th, 2011, with a duration that is at will, has as of this date filed all reports due this office, paid all fees, taxes and penalties owed to the State, that the Secretary of State has not mailed notice to the company that it is subject to being dissolved by administrative action pursuant to S.C. Code Ann. §33-44-809, and that the company has not filed articles of termination as of the date hereof.

Given under my Hand and the Great Seal of the State of South Carolina this 17th day of February, 2026.

Mark Hammond

Mark Hammond, Secretary of State

South Carolina Board of Pharmacy

Nephron SC, LLC
4500 12th Street Ext.
West Columbia, SC 29172

License number: 15200
License type: Manufacturer/Repackager
Status: Active
First Issue Date: 04/23/2014
Expiration: 06/30/2027
Permit Holder: Lou W. Kennedy

File a Complaint against this licensee

No disciplinary action taken by the Board. This certifies that the above licensee is in good standing.

Board Public Action History:

View Orders | View Other License for this Person

No Orders Found

CONTINUATION CERTIFICATE

The SureTec Insurance Company (hereinafter called the Surety) hereby continues in force its Bond No. 3390615 in the sum of One Hundred Thousand Dollars and 00/100 ($ 100,000.00) Dollars,

on behalf of Nephron Pharmaceuticals Corporation

in favor of Nevada State Board of Pharmacy

subject to all the conditions and terms thereof through May 31, 2026 at location of risk.

This Continuation is executed upon the express condition that the Surety's liability shall not be cumulative and shall be limited at all times by the amount of the penalty stated in the bond.

IN WITNESS WHEREOF, the Surety has caused this instrument to be signed by its duly authorized Attorney-in-Fact and its corporate seal to be hereto affixed this 12th day of June, 2025.

SureTec Insurance Company
Surety

By: Angela Y. Buckner
Angela Y. Buckner Attorney-in-Fact

SURETEC INSURANCE COMPANY TEXAS

SureTec Insurance Company
LIMITED POWER OF ATTORNEY

Know All Men by These Presents, That SURETEC INSURANCE COMPANY (the "Company"), a corporation duly organized and existing under the laws of the State of Texas, and having its principal office in Houston, Harris County, Texas, does by these presents make, constitute and appoint

Angela Y. Buckner

its true and lawful Attorney-in-fact, with full power and authority hereby conferred in its name, place and stead, to execute, acknowledge and deliver any and all bonds, recognizances, undertakings or other instruments or contracts of suretyship to include waivers to the conditions of contracts and consents of surety for:

Principal: Nephron Pharmaceuticals Corporation
Obligee: Nevada State Board of Pharmacy
Amounts: **See Bond Form**

and to bind the Company thereby as fully and to the same extent as if such bond were signed by the President, sealed with the corporate seal of the Company and duly attested by its Secretary, hereby ratifying and confirming all that the said Attorney-in-Fact may do in the premises. Said appointment is made under and by authority of the following resolutions of the Board of Directors of the SureTec Insurance Company:

Be it Resolved, that the President, any Vice-President, any Assistant Vice-President, any Secretary or any Assistant Secretary shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

Attorney-in-Fact may be given full power and authority for and in the name of and of behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements or indemnity and other conditional or obligatory undertakings and any and all notices and documents canceling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be binding upon the Company as if signed by the President and sealed and effected by the Corporate Secretary.

Be it Resolved, that the signature of any authorized officer and seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signature or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached. *(Adopted at a meeting held on 20th of April, 1999.)*

In Witness Whereof, SURETEC INSURANCE COMPANY has caused these presents to be signed by its President, and its corporate seal to be hereto affixed this 3rd day of February, A.D. 2023.

SURETEC INSURANCE COMPANY

By: _____
Michael C. Keimig, President

State of Texas ss:
County of Harris

On this 3rd day of February, A.D. 2023 before me personally came Michael C. Keimig, to me known, who, being by me duly sworn, did depose and say, that he resides in Houston, Texas, that he is President of SURETEC INSURANCE COMPANY, the company described in and which executed the above instrument; that he knows the seal of said Company; that the seal affixed to said instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said Company; and that he signed his name thereto by like order.

TANYA SNEED
Notary Public State of Texas
Commission # 128571231
Commission Expires 03/30/2027

_____
Tanya Sneed, Notary Public
My commission expires March 30, 2027

I, M. Brent Beaty, Assistant Secretary of SURETEC INSURANCE COMPANY, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney, executed by said Company, which is still in full force and effect; and furthermore, the resolutions of the Board of Directors, set out in the Power of Attorney are in full force and effect.

Given under my hand and the seal of said Company at Houston, Texas this 12th day of June 2023 A.D.

_____
M. Brent Beaty, Assistant Secretary

Any instrument issued in excess of the penalty stated above is totally void and without any validity.
For verification of the authority of this power you may call (713) 812-0800 any business day between 8:30 am and 5:00 pm CST.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Nephron SC, LLC dba Nephron Pharmaceuticals

Pharmacy/Wholesaler License # (if applicable): WH02295

Physical Address: 4500 12th Street Extension

City: West Columbia State: SC Zip: 29172

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (800) 443-4313 x 2829 Website: www.nephronpharm.com

Licensing Company Email: license@nephronpharm.com

Section 2: Personal Information

First: Lou Middle: Wood Last: Kennedy

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Columbia State: SC Zip: [redacted]

Telephon[redacted] Email: lkennedy@nephronpharm.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of South Carolina		8/80 - 12/84	
Address	**City**	**State**	**Zip**
800 Sumter Street	Columbia	SC	29208
Diploma/Degree obtained, if any			
B.A., Advertising and Public Relations, College of Journalism			

School Name		From - To (MM/YY – MM/YY)	
Lexington High School		8/77 - 5/80	
Address	**City**	**State**	**Zip**
2463 Augusta Hwy	Lexington	SC	29072
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2025 - current	[redacted]	Columbia	SC	[redacted]
1/2015 - 04/2025		Lexington	SC	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Nephron SC, LLC dba Nephron Pharmaceuticals			08/01 to current	
Business Address		City	State	Zip
4500 12th Street Extension		West Columbia	SC	29172
Phone	Title		Number of Employed Hours	
(800) 443-4313 x 2829	President and Chief Executive Officer		40	
Description of Duties				
Resume attached				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Lou Kennedy

[redacted]

Areas of Expertise

Advertising	Management	Training
Public Relations	Sales	Marketing
Recruiting	Customer Relations	Contract Negotiation

Current Position: CEO, Nephron Pharmaceuticals Corporation

- Oversee Company vision and direction
- Responsible for recruiting and training the National Sales Force
- Managing the International Sales efforts
- Oversee large contract negotiations for both vendors and customers
- Facilitate work flow between Sales and Accounting departments
- Strategize with Company Executives to determine future growth and expansion
- Collaboration with Department Heads for pipeline development
- Design and implement Market Research as needed
- Secure Bank Financing and explore liquidity opportunities
- Secure Real Estate as needed for expansion

Work History:

Lou brings to Nephron Pharmaceuticals Corp. more than two decades of experience in the areas of Public Relations, Advertising, and Sales, Management. She has been employed with both large public companies and private entrepreneurial companies that enjoyed explosive growth similar to Nephron.

Education:

B.A., Advertising and Public Relations, College of Journalism, University of South Carolina

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

See attached Nephron Pharmaceuticals resolved disciplinary actions from Colorado and Massachusetts

Original Signature (electronic, copies or stamps not accepted)

01/27/2026
Date

I, Lou Wood Kennedy, **certify that as the designated representative for**

Nephron SC, LLC dba Nephron Pharmaceuticals,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Lou Kennedy
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/27/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lou Kennedy

Print Name (First, Last)

Lou Kennedy

Original Signature (electronic, copies or stamps not accepted)

01/27/2026

Date

Please have this section completed in the presence of a Notary Public.

State of South Carolina, ss. County of Lexington

I, Lou Wood Kennedy, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01/27/2026

Date

Subscribed and Sworn to before me this 27th day of January 2026

Notary Public Signature

Exp: 12/6/2028

BERNADETTE A. HENRY NOTARY PUBLIC SOUTH CAROLINA (Seal)

Nephron SC, LLC dba Nephron Pharmaceuticals
Manufacturer License Application - Employee List

Employee	Job Title
Abstance, Michael c.	STRL RM TECH I
Adams, Hailey N.	EM SFT SPVR
Adams, Lacartay L.	BFS LN TECH I
Adams, Lance L.	OS STR FL TECH I
Adams, Lauren E.	INT
Addy, Bryce T.	FAB WELD
Addy, Haley E.	PROC CAT MNGR
Alexander, Laura M.	MANU PRC INVST
Allegrezza, Christopher J.	EM TECH MGR
Alley, Rubin E.	HP PRNTR OPR
Alston, Quinton	BFS LN TECH I
Altilia, Serena	SR MGR LOE AS
Alvarez, Carlos S.	FRM TECH I
Alvarez, Cynthia P.	QO PRIM PKG TIER I
Amick, Jess K.	RD CHEM I
Anderson, Areonna B.	STRL RM TECH I
Anderson, Martha-Marie P.	SNR GRPH DSN RA
Anderson, Tiesha	MICRO EM TECH I
Archibold, Nicole J.	FRM TECH III
Archie, Katrece L.	OS SHIFT LEAD
Arellano, Allie	Qual Op Spec
Arevalo machado, Harold D.	FAC MAINT TECH
Arevalo, Harold M.	RD MICRO ANLST II
Arevalo, Marjorie C.	SR MICRO QLT SPC
Armitano, Andrew	SLS ADVR
Arrington, Evan W.	OPR TECH I
Arvelo, Emanuel D.	STRL RM TECH I
Asada, Koki	MICRO EM TECH I
Ashe, Gary C.	PRNT SHP MGR
Ashford, Brian	BFS LN TECH I
Aughtry, Rodney D.	BFS MAINT TCH II
Avant, Jaxon	INT
Ayers, Erica J.	RD CHEM II
Babinchak, Ashley A.	VAL ENG
Baccus, Derek E.	STERL RM SUP
Baker, Abigail G.	MICRO EM TECH I
Baker, David	STBL OP TECH II
Baker, Stephanie	QS SCI MGR
Banks, Krystal	OS STR FL TECH I
Barajas Martinez, Kenia	FRM TECH I
Barber, Ambrina E.	COMP ASSY TECH
Barber, Travis R.	FRM TECH II
Barboza, Tyler T.	SR DIR FLLNG STER
Baston, Sharon D.	COMP ASSY TECH

Nephron SC, LLC dba Nephron Pharmaceuticals
Manufacturer License Application - Employee List

Employee	Job Title
Bates Butler, Lyne B.	QO PRIM PKG TIER I
Baxter, Jamal T.	OPR TECH I
Beck, Bryan P.	CHF TECH OFF
Beckett Jr, Michael D.	FAC MAINT TECH
Beckett, Sean M.	RD CHEM II
Beeks, Antoinett L.	BRR CONT IMP SP
Beerman, John E.	FILT PROG SUPRV
Behling, James H.	TERR SLS MGR
Belton, Misty R.	QO SEC PKG 503B
Belton, Sabrina R.	QO SCPK SUP
Belton, Sirdell A.	BFS MAIN TECH
Belue, Flavoris	MICRO QLTY INVST
Beneker, Chad M.	RD EXT AN LEAC MNGR
Bennett, Brian R.	QC CHTEC
Bennett, James A.	SALESADVISOR
Beres, Danielle R.	ANLY CHEM II
Berry, Jashawn	STRL RM TECH I
Bhadane, Nikhil V.	QO MNG SHOP FLOOR
Bilka, Lauren	503B OPS SUP
Bissoondyal, Amarnath	VP MANUF
Black, Jared D.	BFS LN TECH I
Blake, Shanae J.	VIS INSP OPS TRNR
Blizzard, William D.	BFS MAINT TCH II
Bloom, Lindsey T.	RD MICRO ANLST II
Bogdon, Raymond K.	MANU PRC INVST
Bond, Ta'Vonne	MGR IN TRNG
Boone, Annie C.	503B OPS TCH
Bosket, Lashonya C.	QO VIS INS Tier III
Bowen, Joseph C.	SR IT BUS SYS ANLST
Bowie, Flynn F.	LD MFG INV
Branham, Andrea S.	QO SEC PKG WRHS MGR
Branham, Philip E.	ORDR FFLMNT SPEC I
Branham, Sam M.	DOC CTRL SUPR
Braxton, Jimmie W.	ENG INVNTRY MNGR
Briggs, Brian D.	ANLY CHEM I
Brooks, Demonta s.	QO VIS INS Tier III
Brooks, Faron E.	FAC MAINT TECH
Brown, Angela M.	CLN RM QA TIER I
Brown, Dwayne A.	COM TECH
Brown, Rolando R.	PROCRMT SCM
Brown, Shannon Z.	SEC PKG MAINT TECH I
Brown, Thandeka	QO SCPK LD
Bryant, Amya D.	OS OPR ASSC
Buckley, Deborah K.	QO PRIM PKG TIER II

Nephron SC, LLC dba Nephron Pharmaceuticals
Manufacturer License Application - Employee List

Employee	Job Title
Bullard, Connie L.	STR RM MAT TRNS TECH
Bundrick, John D.	REG AFFR PHRM MGR
Burkett, Adrian E.	QO SCPK Tier I
Burnham, Gregory J.	0
Burns, Binh N.	ANL SRV TECH MGR
Butler, Carla E.	QO PMPK SR
Butler, Madison D.	SLS ADVR
Byars, Tammy L.	CF ACCT OFCR
Byland, Cynthia M.	SR VP PROD LDR S
Byrd, Kameko D.	OS STR FL TECH I
Cain, Aubrey R.	SNR DIR STRILTY ASR
Calatrava, Junnell B.	FRM TECH I
Caldwell, Traci L.	STR RM MAT TRNS TECH
Calliste, Michael M.	QO ASPTC SPVR
Calloway, Gidget R.	QO VIS INS Tier III
Camis, Yariel	DIR OF CAL
Camp, Roy N.	QO PMPK MGR
Canepa, Jonah A.	MANU PRC INVST
Cannella, Josh L.	CNC MACHIN
Cannon, Terrenzio T.	STRL RM TCH II
Capodacqua, Frank T.	TERR SLS MGR
Cardenas, Micah-Jeuxrell B.	QO SCPK Tier I
Cardoza, Jana G.	CHNG CNTRL QA SPEC
Carey, Amelia K.	HR ADMIN
Carpenter, Allison A.	HR ADMIN ASST
Carrera, Emily M.	VP of QLTY RISK MGMT
Carter, Daniel T.	MGR OF FORM
Carter, Dominic D.	FRM TECH I
Casassa, Nathan C.	SMQC
Castles, Victoria C.	TRN COORD PRODUCTION
Cavanaugh, Zachary R.	FORM SCI
Cave, Catherine H.	SNR MNFCT INV
Cepero, Zahira	VP VALID
Chadmon, Jamela A.	OUTS ASS LINE MNGR
Chapman, Landon J.	RM WHS TECH I
Chavis, Todd	BFS LN TECH I
Chen, Jacqueline	DIR IT SERV
Chumanevich, Alena	ANLY CHEM II
Chumanevich, Alexander	ANLY CHM III
Clark, James B.	RSN SUPV
Clark, Scott D.	ORDR FFLMNT SPEC I
Clark, Shakeena T.	TCHR
Colbert, Miles D.	INFO SYS DEV
Coleman, Christian M.	ORDR FFLMNT

Nephron SC, LLC dba Nephron Pharmaceuticals
Manufacturer License Application - Employee List

Employee	Job Title
Coleman, Mya N.	ANLY CHEM II
Coleman, Trey L.	EM ASST MNGR TRAIN
Collins, Renee D.	QO VIS INS Tier III
Compton, John E.	BFS LN TECH I
Conner, Caleb F.	RD CHEM II
Conwell, Amy W.	ITC
Cooper, Jason S.	SEC PKG MAINT LD
Cooper, Lewis P.	OPR TECH I
Cooper, Rajay T.	PROD CHNG CNTRL MNG
Corley, Alex S.	MANU PRC INVST
Corley, Kyle K.	DIR OF OPR
Corley, Miriam C.	QUAL CONT IMP MNGR
Corley, Phillip K.	SCNDRY PCK MAIT MNGR
Corley, William A.	OPR TECH I
Craft, Tanner N.	ORDR FFLMNT SPEC I
Crespo, Angel M.	OPR TECH I
Cromer, Rebecca L.	BRR SUP
Crouch, Joseph E.	FAC MAINT TECH II
Crowetipton, Jared M.	ASSRDM
Curry, LaPaula D.	STR RM MAT TRNS TECH
Cutler, Jill A.	PharmD
Cuttino, Maria C.	QO SEC PKG 503B
Dadawalla, Sarah	INT
Dallman, Lucy C.	QS SNR DPQC SPC
Daniels, McKenna G.	PAYRL
Das, Shawtik C.	RD CHEM II
Daugherty, Ashley B.	CORP CHF QUAL COMPL
Davenport, Brett S.	SEC PKG MNT TECH II
Davenport, Lyndi G.	INT
Davis, Endia	OPR TECH I
Davis, Jeremy W.	OPR TECH II
Davis, Michelle P.	STBL SPC TIER I
Davis, Rodquel G.	RD MICRO ANLST I
Davoudi-Fleischer, Neda	QS SCI SPC TIER III
Dayson, Eric M.	WHS OPR III
Del Campo, Kevin J.	QS SCI SPC TIER III
Delaney, Heather S.	WHSE LOG SPC
Deleon, Alyssa D.	DOC CNTRL SPC I
DeLoach, Cortina L.	QO TRNG COORD
DelSpina, Brandon M.	AUTOMN ENGR
DeLuca, Brandon T.	MICRO LAB TECH
Derrick, Kessler	PIC
Diamond, John P.	SR ENG PROJ MNG
Diaz Macias, Zaidy B.	EXC AFRS ASST

Nephron SC, LLC dba Nephron Pharmaceuticals
Manufacturer License Application - Employee List

Employee	Job Title
Dickson, Ebony N.	QO SCPK TRNR
Diggle, Sloan	STRLTY ASR PROJ MNGR
Diimmler, Jason K.	SEC PKG LEAD LINE TE
Dingle, Altrina M.	COMP ASSM LD TECH
Dix, Anna L.	503B OPS TCH
Dixon, Anastasia	RD CHEM II
Dixon, Leah C.	CHNG CNTRL QA SPEC
Dixon, Richard E.	EM ASST MNGR TRAIN
Domin, Joshua P.	FORM SYS MAINT TECH
Donahue, Tracie M.	QO SCPK Tier II
Dotson, Cooper D.	ENGR
Dougherty, Brandon W.	UTL MNT TECH
Draper, Caitlin	QO VIS INS Tier III
Dubose, Travis L.	QC MICRO SHFT LD
Duckson, Sheralynn	STR RM MAT TRNS TECH
Dukes, Alma J.	QO SCPK LD
Dukes, Stacey D.	WHSE LOG SPC
Duncan, Joseph C.	SR IT STM ANLS
Duncombe, Shania	SNR ACCNT
Dunning, Cassandra N.	QO PRIM PKG TIER II
Dyar, Kay K.	ORDR FFLMNT LEAD
Dyckes, Jordan M.	MICRO EM TECH I
Eargle, Leon	STRL RM TECH I
Easterday, India M.	OS ASPT TRNR
Edmundson, Heather K.	QC MICRO SHFT LD
Edwards, Joseph T.	MANU PRC INVST
Elling, Tyler	IT EBR SYSTM SUPRV
Elliott, Jasmine L.	ANLY CHEM I
Elmore, Tisheema R.	STRL RM TECH I
Elwell, Hunter J.	MICRO LAB EQUIP MNG
Emerson, Michael D.	SEC MGR
English, Camille C.	INT
English, Sharon D.	E80 WHSE LD
Erazo, Luisa D.	STRL RM TECH I
Escobar, Johanna	FRM SPRV
Escobar, Rene	BFS SHIFT SPR
Etheredge, Corey T.	FRM LEAD
Evans, Ashley S.	STR RM MAT TRNS TECH
Evans, Tierra	STRL RM SUPV
Everson, Benjamin D.	FAC MAINT TECH
Fanning, Latrisha D.	STRL RM TCH II
Farmer, David A.	FORM SYS MAINT TECH
Farr, Les	UTL MNT TECH
Faust, Gary C.	FRM TECH III

Nephron SC, LLC dba Nephron Pharmaceuticals
Manufacturer License Application - Employee List

Employee	Job Title
Faust, Jalen	STRL RM SUPV
Felder, Katie B.	STBTYMGR
Feliciano, Brooke M.	INT
Ferguson, Antonio D.	CLEANLD
Fineberg, David C.	TERR SLS MGR
Fisher, Jeffrey A.	LD FABRC WLD
Fitzpatrick, Elizabeth R.	IT VALD MGR
Floyd, Andre M.	OPR TECH I
Floyd, Tyler D.	OPR TECH I
Folsom, Christopher T.	ASS CHF ADMIN OFF
Fontes, Derrick M.	FAC MAINT TECH
Ford, John E.	EM TECH MGR
Forrester, John A.	CLBR TECH
Foster, Ashley L.	IT STMS ANLST I
Foster, Jeremy S.	MGC
Foster, Jessica D.	FRM TECH III
Fowler, Jimmy L.	MICRO LB INVTR COORD
Francis, David A.	INT
Freeman, Cassandra L.	DIR SUPP QLTY
Friedman, David L.	DIR OF FP
Frost, Michelle L.	DIR DOC CNTRL
Frownfelter, Karen L.	SEC PKG SUPR
Frye, Tamara E.	QO VIS INSP TRN SUPR
Fuller, Krysanna K.	MICRO EM TECH I
Furtick, Kendall R.	MAIN TECH
Gainey, Charles W.	MACHIN
Gallman, Darius T.	MICRO EM TECH I
Gamble, Devin J.	MICRO EM TECH I
Gantt, Jami	ANL SRV CTRL SUB AS
Garcia, Kayla L.	FRM TECH I
Gardiner, Christopher E.	DISTBN CNTR MNGR
Garner, Alexandra L.	DIR OF EXEC AFFR
Garrett, Aden B.	IT EBR STM ANLST
Garrett, Briana T.	SQS
Garzarella, Jillian N.	ENGR
Gault, Kathryn M.	0
Geiger, Alexis B.	VALDN SPEC
Geiger, LaKeisha P.	QO SCPK Tier II
Geiger, Shatora A.	QO PMPK SR
Geith, Julia	QS INVS TIER I
Gentry, Cierria J.	QLTY OP VIS INSP SUP
George, Brenda K.	FAC UTL OPR MGR
George, Delari J.	VP FACIL
Gerard, Taylor M.	MICRO TRNG SUPV

Nephron SC, LLC dba Nephron Pharmaceuticals
Manufacturer License Application - Employee List

Employee	Job Title
Golston, Sameria S.	QO SR VIS INSP
Gomez Altuve, Andreina B.	DIR STRLTY ASSR
Goodson, Melvin B.	CST ACCNT FIN ANYL
Goodwin, Michael B.	BFS LINE MNG
Goodwin, Olanda D.	QC Chem QLTY SPL
Gorman, Thomas C.	LD INT AUD
Graham, Curtis L.	BFS LN TECH I
Graham, James E.	SEC OFCR
Graham, Tarez J.	ASP PROCS SIMULTN SP
Grass, Christian L.	ENGR
Gray, Kayla L.	RTL PHRM TECH
Green, Dominic L.	BFS LN TECH II
Green, Lorraine N.	STRL RM COOD
Green, Trigere D.	FILT PROG SPEC
Greene, Brian W.	Welder
Greene, Miranda	ACCT REC ANA
Greer, Dillon B.	ANLY CHM III
Gridine, Sonya B.	QO SCPK LD
Hadder, Thomas W.	QO PMPK ASM
Hagenbuch, Isaac M.	QS SCI SPC TIER III
Hagood, Rickey G.	BFS LN TECH I
Hale, Courtney A.	ORDR FFLMNT LEAD
Hall, Jada R.	QO PRIM PKG TIER I
Hall, Matthew L.	FACPER
Hall, Shavon S.	MICRO SMPL MNGT SUP
Hallman, Latonji G.	QO SCPK Tier II
Hammonds, Freddie P.	OPR TECH II
Hammons, John D.	BFS LINE MNG
Hanes, Morgan G.	QC SUP MGMNT SPC II
Hansen, Caroline D.	DIR REG AFAIR
Harris, Hakeem	STRL RM TCH II
Harris, Tiger	BFS LN TECH I
Harrison, Carlo E.	STRL RM OPS MNGR
Harrison, Daniel S.	OPR TECH I
Hart, Trace R.	ENGR
Hartley, Amanda N.	IT PRJ COORD
Harvin, Monique M.	DIR QLTY COMP
Hawes, Amanda M.	ANL SRV SPEC PRJ CRD
Heinen, Charles A.	FRM SPRV
Heinrich, Bobby	SEC PKG MAINT TECH I
Helms, Ashley E.	INT
Hemmer, John K.	SEC PKG SR MGR
Henderson, Carlie K.	QS INVS TIER I
Hendrix, Doyce W.	WHS OPR

Nephron SC, LLC dba Nephron Pharmaceuticals
Manufacturer License Application - Employee List

Employee	Job Title
Henry, Bernadette A.	REG AFR LIC SPEC
Henry, Brianne A.	BRR
Henry, Darriel	BFS LN TECH I
Henry, Donetta D.	BFS CHNGOVR SPEC
Hermosillo, Amanda D.	TERR SLS MGR
Hernandez Rivera, Nathaly L.	ANLY CHEM II
Herndon, Aubrey A.	PROCR SPC
Hill, Evangeline B.	FRM TECH III
Hill, Jeffrey A.	FORM TRNR
Hill, Rashada	OS SUPERVISOR
Hinson, Hunter D.	LLCCA
Hite, Lindsey K.	ANLY CHEM II
Hodges, Kawanna M.	QO PRIM PKG TIER III
Hopkins, Saprina W.	BRR
Hough, Evelyn A.	CL RM QA TRNR
Howell, Marvin M.	BFS LN TECH II
Howell, Maurice L.	STRL RM TECH I
Hudgins, Christie S.	QC SUPP SPV
Hudson, Wilder J.	TERR SLS MGR
Hulteen, Brandt C.	QO CLN RM SR MGR
Hunter, Tiffany S.	QO SCPK Tier II
Hurt, Lena M.	MICRO DMC
Hutchinson, Cynthia	OPR TECH I
Igbokei, Edward B.	BFS LN TECH I
Jackson, Eric J.	LNSSA
Jackson, Monett D.	QO PRIM PKG TIER I
Jacobs, Carlton	QO PMPK SR
James, Flexica M.	QO SR VIS INSP
Jeffcoat, Ashley N.	SR QC LAB SYS ANLYST
Jeffcoat, Kelvin A.	503B OPS TCH
Jefferson, Donovan J.	STRL RM LED
Jenkins, Alsenio D.	503B OPS TCH
Jenkins, Shanika N.	STR RM MAT TRNS TECH
Johns, Samuel M.	QO PRIM PKG TIER I
Johnson, Andrene	BFS LN TECH I
Johnson, Ashley N.	TERR SLS MGR
Johnson, Camila	OS STR FL TECH I
Johnson, Clive	QA CHNG CNTRL SR MNG
Johnson, Jahki R.	QO SR VIS INSP
Johnson, Jazmin M.	QO PRIM PKG TIER II
Johnson, Mamie R.	QO PRIM PKG TIER I
Johnson, Tammy L.	EXC AFRS ASST
Jolly, Tracy S.	SEC OFCR
Jones, Christian F.	FAC MAINT TECH II

Nephron SC, LLC dba Nephron Pharmaceuticals
Manufacturer License Application - Employee List

Employee	Job Title
Jones, Frederick A.	OPR TECH I
Jones, Jeremiah K.	ANLY CHEM I
Jones, Joseph M.	HP PRNTR OPR
Jones, Kiashia D.	OS STR FL TECH I
Jones, Tammy M.	QO PMPK SPRV
Jones, Taryn B.	QO ASPTC COORD
Joyner, Dazha T.	503B OPS LEAD TCH
Keisler, Dane M.	OPR TECH II
Kelly, Ayanna F.	MICRO EM TECH I
Kennedy, Brittany A.	DOC CNTRL SPC I
Kennedy, Lou W.	CEO
Kernan, Morrisey A.	TERR SLS MGR
Kershaw, Robert H.	QLTY OP VIS INSP SUP
Killingsworth, John J.	SR IT STM ANLS
Killman, Jackson A.	STRL RM TECH I
Kirk, Joshua P.	BFS MAINT TCH II
Kitchens, Matthew	COM TECH
Knight, Christian M.	QO Shop Floor Specia
Koppang, Paul V.	CF FIN OFF
Kotti, Burton D.	PRODSUPV
Kouameni, Christelle N.	QLTY OP VIS INSP SUP
Kraft, Nicolas A.	SEC PKG MNT TECH II
Kraft, Ryland J.	OPR TECH I
Kropp, Michael	DIRECT OF LOG
Kummer, Markus	MCH SHP ASST DIR
Lacas, Ritu	PharmD
Lalande, Roxanne	STR RM MAT TRNS TECH
Lano, Morgan A.	CMC REG AF SR ASS
Lava, Kenneth A.	RD MICRO ANLST I
Lavin, Andres	OPR TECH I
Lee, Kaitlyn V.	MICRO DTA ANLST
Lee, Lisia T.	QO PRIM PKG TIER I
Leebrick, Devon	QO PRIM PKG TIER I
Lefever, Olivia J.	INT
Lever, Sue A.	TRNG COORD GEN
Lewis, Harley H.	BFS LINE MNG
Leysath, Nigel N.	QO PRIM PKG TIER I
Liang, Weixiong	RD CHEM II
Liberti, Luke J.	CNC MACHIN
Lincoln, Tinnie R.	QO CLN RM SPRV
Liyanage, Madhuka V.	RD CHEM II
Locker, Aprille L.	DIR MICRO BIO
Lockhart, Japa J.	MICRO EM TECH II
Locklair, Kay F.	INTRNL AUDT

Nephron SC, LLC dba Nephron Pharmaceuticals
Manufacturer License Application - Employee List

Employee	Job Title
Longstaff, Jennifer	VP OF PRODUCTION
Lopez, Rocendo	MC QLTY INV
Lowe, Rayana	MICRO EM TECH I
Lucas, Haley P.	QUAL COMPL IMPRV MGR
Lugo, Karime N.	FRM TECH III
Lunagariya, Paras	CLN RM QA TIER I
Lutinski, Katie J.	MC QLTY INV
Lynds, Michael T.	BFS LEAD LINE TECH
Mack, Charlene	OS SUPERVISOR
Mack, Johnny C.	SMNS
Mack, Rosa L.	QO PRIM PKG TIER I
Mack-Baccus, VICTORIA S.	QO PRIM PKG TIER I
Maddox, Hanna T.	ORDR FFLMNT SPEC I
Maliedje Noubissi, Denise R.	QO SCPK SUP
Malinder, Kimora A.	OPR TECH I
Mallory, Anthony C.	SEC OFCR
Manigo, Jamaal R.	STRL RM TRNR
Manley, Quinn P.	SLS ADVR
Mann, Kristina M.	ANLY CHM III
Margraf, Kristy D.	BRR
Marshall, Keeyona D.	STRL RM TECH I
Martin, Devar	CLN RM QA TIER I
Martin, Micheal W.	CNC MACHIN
Martin, Miles C.	API WAHO SUP
Martin, Terrance R.	BFS LN TECH II
Martinez, Erick	COM TECH
Mason, Alisa	STRL RM TCH II
Matthews, Megan N.	BRR
Mattox, James D.	QO PMPK SPRV
Maxfield, Josh A.	WHS OPR III
Maxwell, Sheldon K.	FRM TECH II
Maybank, William A.	CHNG CNTRL SR QA SPE
McCall, Rene	CRE DIR
McClelland, Emma M.	LAB SYS ENG
McCoon, Ross S.	ANLY CHEM II
McDaniel, JaDiamond	STRL RM TECH I
McDaniel, Tyler P.	QO CLN RM QA COORD
McElveen, Lee V.	CLN RM QA TIER I
Mcfadden, Kenneth S.	OS STR FL TECH I
McFadden, Tvon M.	FRM SPRV
McFall, Sarah W.	PROCRMT SCM
McLaurin, Bryce H.	INFO SYS DEV
McNeese, Benjamin J.	LD FABRC WLD
Means, Nathan A.	BFS LN TECH I

Nephron SC, LLC dba Nephron Pharmaceuticals
Manufacturer License Application - Employee List

Employee	Job Title
Mefford, Jonathan D.	ORDR FFLMNT SUP
Mefford, Lauren S.	PD SPM
Mefford, Michael A.	QA PROS OPT SPEC
Mendoza Ramirez, Felipe D.	RD CHEM I
Mergo, Joseph G.	CHIEF ADMIN OFF
Merritt, William C.	BFS LN TECH I
Messex, Brent P.	AUTOMN ENGR
Metts, Michelle G.	EXEC DIR QUAL ASSR
Meza-Prokop, Fran F.	INSTR COORD
Micol, Anne-Marie B.	DIR QA INVEST
Miller - Ostrom, LaDonna K.	PAYRL MGR
Miller, Michael A.	DEA COMP MGR
Mims, John A.	RD OPR SUPV
Mitchell, Kayla M.	OPS TCH III
Moody, Wynton	BFS LN TECH I
Moore, Latavia P.	MICRO ANLST II
Moore, Myron	WHS OPR II
Moore, Victoria M.	RD CHEM II
Moore, Zaria D.	QO MMSP
More, Nishigandha Milind	FRM TECH I
Morgan, Micah	MANUFACT COORD
Morrison, Emily E.	MICRO DTA ANL LD
Moss, Randy S.	OPR TECH I
Murrin, Christopher W.	CHF HR OFF
Myers, Nalessia B.	STRL RM ASST MGR
Nance, Caroline J.	TDC
Nario, Myrna V.	QO SCPK Tier I
Nazzery, Shannon T.	WHS OPR
Neal, Tammy L.	TERR SLS MGR
Neese, Debra D.	SDQ
Nelson, Daniel G.	ANLY CHEM II
Nesbitt, Shanika D.	DOC CTRL SUPR
Neuburger, Brandy	ACCT PAY ANLST
Nguyen, Helen T.	FRM LEAD
Nguyen, Lam	INFO SYS DEV
Nicolas, Marie F.	BRR
Nieves, Edson D.	CLBR TECH
Nieves-Perez, Luis E.	VALDN SPEC
Njaprim, Godwin k.	CLN RM QA TIER I
Noubissi, Innocent	QO SCPK SUP
Novoa Delgado, Muskendol	ANLY CHEM II
Nunes, Haylee M.	QC CHEM OPERAT SUPRV
Obaidan, Mohammed A.	ENGR
Oglesby, Kenneth A.	FAC MAINT TECH

Nephron SC, LLC dba Nephron Pharmaceuticals
Manufacturer License Application - Employee List

Employee	Job Title
Ohonjo, Diana A.	ANL SRV RD CT PRG MG
O'Leary, Jo Ann	OPS TCH III
O'Neill, Erin E.	CMC
O'Quinn, Keith M.	SEC OFCR
O'Shaughnessy, Leah B.	DIR SALES OPS
Oswalt, Robby A.	SEC OFCR
Otasowie, Efosa M.	DEF
Owens, Matt E.	MGC
Paladino, Melanie S.	FRM TECH I
Palapolu, Rajyalakshmi	QS INVS TIER I
Palmer, Ian A.	RD TECH SUPRV
Palmer, Sophia	QLTY OP VIS INSP SUP
Parab, Sejal Sandeep	CLN RM QA TIER I
Parab, Sejal Sandeep	CLN RM QA TIER I
Paradise, Gabe L.	IT SFTWR DVLPR
Parker, Casey L.	FAB WELD
Parker, Sharolyn D.	STRL RM TECH I
Patel, Ankitkumar M.	RD SPEC PRJ SC
Patel, Avaniben N.	ANLY CHEM II
Patel, Payal D.	DIR DOC AND CHNG CNT
Patel, Pinal	MICRO ANLST I
Patel, Pratikkumar R.	REG AFR ASSO
Patel, Preeti	FRM TECH I
Patel, Priyankkumar A.	QO PRIM PKG TIER I
Patel, Radhika P.	MICRO ANLST I
Patel, Riddhi P.	ANLY CHM III
Patel, Sejal S.	BRR
Patel, SWATIBEN	STBL SPC TIER I
Patel, Trushnaben B.	ANLY SER TRAIN MGR
Peart, Elijah C.	MICRO EM TECH I
Pegden, Randall S.	QC CHEM OPERAT SUPRV
Penaloza, Maria	FRM TECH III
Pepper, Patricia T.	CLN RM QA TIER I
Perrot, Kenneth D.	BFS LN TECH II
Perry, Caitlin M.	QO MMSP
Peterson, Tamika A.	AS LOG MNGR
Phillips, Molly V.	VAL ENG
Piechota, Frank J.	VP OF QUALITY
Pinkston, Zakia L.	QO PRIM PKG TIER I
Pippin, Zach Z.	VID PROD SPC
Platt, Brian B.	SMSD
Platt, Linda S.	BRR TRN CORD
Polacek, Gregg A.	TERR SLS MGR
Porter, Donald C.	RD SNR SCI

Nephron SC, LLC dba Nephron Pharmaceuticals
Manufacturer License Application - Employee List

Employee	Job Title
Post, James A.	SEC PKG MNT TECH II
Potts, Taylor Rae	ANL CHEM LD
Pough, Shanika A.	BFS SUPP SPE
Pradubsri, Jo A.	STRL RM LED
Price , Michael	QO WHS
Price, William C.	TERR SLS MGR
Priester, Terry D.	WHS OPR III
Priester, Tobarcus S.	503B OPS SUP
Prioleau, Charles E.	OPR TECH II
Pritchard, Donald H.	QO MMSP
Pritchard, Floyd G.	CNC MACH LD DSGN
Pryce, Lee-Ann A.	MICRO EM TECH I
Pryor, Justin M.	QO WHS
Quigley, Daniel A.	QC CHEM OPERAT SUPRV
Raccolin, Sophia R.	HRGEN
Rainsford, Melissa M.	STF DVLP MGR
Rameas, Julie R.	CHF PROC OFF
Rankine, Jasmine J.	SNR MNFCT INV
Ratchford, Zion A.	MICRO EM TECH I
Ravula, Jyothi prasad goud	CLN RM QA TIER I
Ravula, Jyothi prasad goud	CLN RM QA TIER I
Ray, Dennis L.	BFS MAINT TCH II
Raysor, Kyiana S.	CLN RM QA TIER II
Reckhow, Michael J.	SEC PKG SUPR
Reed, April	SR VP QUAL ASS
Reed, Michael R.	QC CHEM INV SPEC
Regis, John	CLN RM QA TIER I
Reid, Yolanda D.	SEC OFCR
Rey, Francisco	UTL MNT TECH
Reynolds, Katie M.	MICROPROMGR
Reynolds, Rebecca A.	503B OPS SUP
Rhodriguez, Kabria B.	PROC GENRLST
Rice, Alisa S.	BFS LN TECH II
Richardson, Cateena E.	BRR SUP
Richburg, Andrea R.	IT SFTWR VA ANALYST
Riggins, Ronnie J.	LD PRC TCHN
Rikard, Richard A.	BFS MAIN MGR
Riley, Lea A.	QC MICRO QTY SPEC
Rish, Stephanie M.	RD CMC REG SCI
Robinson, Andre K.	OS OPR MGR
Rogers, Lance E.	EXEC VP MANF TCH SRV
Romero, Michelle	MICRO EM TECH I
Rothbell, Amelia P.	HRGEN
Rourke, Conor J.	IT EBR STM ANLST

Nephron SC, LLC dba Nephron Pharmaceuticals
Manufacturer License Application - Employee List

Employee	Job Title
Rowley, Grace J.	RTN MGR
Rumph, Phillip	BFS LN TECH I
Rush, Rayford G.	BFS LN TECH I
Rutherford, Nikki L.	BFS LN TECH I
Ryckebosch, Peter	VP WARE LOGS
Sabaka, Kelli S.	OPR TECH I
Sackel, Akheem M.	BFS SHIFT SPR
Sackel, Melissa A.	QO PRIM PKG TIER II
Salon, Starleen Joy Rojas	MICRO EM LEAD
Santulli, Alexander C.	RD SNR SCI
Savage, Angel M.	BFS LN TECH I
Sawyer, Vincent	BFS LN TECH I
Scott, Cassie N.	DOC CNTRL SPC I
Scott, Dakota	MICRO SMPL MGMT CLER
Seawright, Varmiko T.	STR RM MAT TRNS TECH
Sedor, Kaitlyn E.	INT
Semidey Flores, Jose M.	FILT PROG MNG
Seymour, Susan B.	TRNG DEV DIR
Shaw, Bruce W.	AS SERV LAB INVS MGR
Sheard, Helen M.	QO PRIM PKG TIER I
Sherman, Bryant C.	OPR TECH I
Sherrod, Laceasar A.	ANLY CHEM I
Shiggs, Sha'Keela	MICRO LAB TECH
Shoup, Douglas M.	ENVR COORD
Shuler, Franchesca L.	QO PRIM PKG TIER I
Shuler, Marilyn S.	QO VIS INS Tier III
Simmonds, Stephanie L.	CHF COMPL
Simon, Tricia A.	RD CHEM II
Sims, Antonio R.	ORDR FFLMNT SPEC I
Sims, Brett	SEC OFCR
Sims, Darren M.	STRL RM TCH II
Singleton, AunQuaisha S.	STRL RM TECH I
Sledge, Virginia B.	PD PRJ MGR
Sloan, Doug M.	BFS MAINT TCH II
Smith, Adam C.	BFS TRNR
Smith, Byron J.	BFS SHIFT SPR
Smith, Derek R.	WHS OPR
Smith, Enaida	QO PRIM PKG TIER I
Smith, Jennifer L.	QO SCPK Tier II
Smith, Joseph E.	QO VIS INS Tier III
Smith, Kyle C.	OPR LD TECH
Smith, Michelle F.	STRL RM TECH I
Smith, Reed K.	QUALITY BRR PHARM
Smoak, Walter L.	NSS

Nephron SC, LLC dba Nephron Pharmaceuticals
Manufacturer License Application - Employee List

Employee	Job Title
Snuffer, Bobby P.	SEC OFCR
Sorcia, Tomas	FRM SPRV
Sorsby, Turner S.	QO MMSS
Soto, Radames	FRM TECH II
Sox, Mary Lynn	HOSPITALITYMGR
Spann, Rana J.	QO SCPK SUP
Speaks, Jennie R.	FILT PROG SPEC
Spencer, Johnquanek N.	MICRO EM LEAD
Spires, Jamie L.	QOMMM
Spotwood, Andrae M.	FRM LEAD
Sprouse, Marissa J.	EM TECH TRNR
Spruill, Michael L.	INSTRMN SPEC
Spry, Christian J.	MANU OPS SYS SPRV
Squirewell, Curtis G.	FAC MAINT TECH II
Stafford, Jessy M.	ANL SRV SR INVS SCI
Steele, Kayla	QO SCPK Tier III
Stiltner, Lindsey	QSSC
Stoudenmire, Kurt A.	FORM SCI
Strange, Pamela L.	QO PRIM PKG TIER I
Stringfellow, Demisha S.	QC MICRO PRO MGR
Stuckey, Frances G.	QO MMSS
Studer, Reed A.	STRL RM TECH I
Sturkie, Rebecca L.	UPM
Sumani, Sanikonda	OPR TECH I
Summers, Tanekqua L.	SEC OFCR
Sumter, Annie L.	COMP ASSY TECH
Sumter, Leon D.	BFS LN TECH II
Sutler, Anthony P.	STRL RM TECH I
Swanson, Amy A.	QUAL COMP PRJT MNG
Syphertt, Marquis A.	BFS LN TECH I
Szewczyk, Richard	ENGR MGR
Taylor, Destiny I.	QO SEC PKG 503B
Terrapin, Coleman F.	ENGR
Thekke Kottarathil, Vinod K.	VP MICRO
Thomas Sr., Anthony B.	BFS LEAD LINE TECH
Thomas, Dorian L.	BFS LN TECH II
Thomas, James A.	SEC PKG SUPR
Thomasson, Zach S.	WHS INV MGR
Thompson, Dequan A.	STERL RM SUP
Thompson, Patanza l.	OS STR FL TECH I
Thomy, Casey S.	MICRO INVSTG MGR
Thomy, John M.	SNR CUST CR MGR
Thornton, George D.	MICRO ANLST I
Thornton, Reilly A.	OS STR FL TECH I

Nephron SC, LLC dba Nephron Pharmaceuticals
Manufacturer License Application - Employee List

Employee	Job Title
Thornton, Tyana M.	GWM CERTF COORD
Tidwell, Bradley R.	REG AFFR PRJ MGR
Timbers, Sahar S.	SEC PKG LEAD LINE TE
Toatley, Brandon	BFS LN TECH I
Toomer, Deirdre E.	ASP PROCS SIMULTN SP
Toro Bosque, Magalis	AS SNR MNGR INSTR
Trapp, Cornelius E.	503B OPS LEAD TCH
Traufler, Joshua B.	SEC PKG MNT TECH III
Trotter, Luke M.	SECPKMGR
Tucker, Stephanie G.	ACC PYBL MGR
Tufi, Tanaya A.	MICRO EM TECH I
Turner, Larry A.	SEC OFCR
Turner, Ryan K.	ORDR FFLMNT SPEC I
Tyler, Duane K.	STRL RM LED
Tyson, Tiesha A.	RD SPEC PRJ CRD
Uischner, Andrea V.	STBL OP TECH I
Unger, Christian A.	SQSI
Urbates, Harrison J.	ORDR FFLMNT SPEC I
Valladares, Efrain E.	COMP ASSY TECH
Van Alstine, Joshua T.	BUS CTRL
Van Deusen, Chase J.	BFS LN TECH I
VanderHeide, Curtis	BFS LINE MNG
Vasa, Aditya S.	FORM SCI
Vaughan, Brandon E.	BFS LINE MNG
Villegas Sanchez, Kayly	OPR TECH II
Vining, Rachel A.	FORMMGMT
Wadlow, Paul	EXEC VP OF OPS EXCEL
Walker, Jennifer	STRL RM TCH II
Walker, Rashaun T.	OS STR FL TECH I
Walker, Teaonna M.	STRL RM LED
Walls, Christopher L.	IT DB ADMIN
Walt, Eric N.	QO PMPK SPRV
Walters, India	FILT PROG SPEC
Wannamaker, Keyerica J.	MICRO EM LEAD
Washington, Curtis	WHS OPR II
Waters, Brayden G.	FRM TECH I
Watkins, Debra	QO SCPK Tier I
Watters, Rodney D.	WH LEAD
Watts, Gary A.	QO WHS
Watts, John R.	FAC MAINT TECH II
Weaver, Tandra T.	MICRO ANLST I
Weber, Kimberly A.	OS STR FL TECH I
Wells, Antonio D.	FRM TECH I
Wessinger, Anita Z.	ACCT MGR

Nephron SC, LLC dba Nephron Pharmaceuticals
Manufacturer License Application - Employee List

Employee	Job Title
Wheeler, Alliyah L.	QO PMPK SR
Whisenant, Avery C.	INT
White, Peighton E.	INT
Whitehead, Mark G.	UTL MNT TECH
Whitmore, Nancy	QO SCPK Tier II
Whitsett, Hanna S.	SALES ACCT MGT
Wicker, Kennedy W.	SNR MNGR ENG
Wideman, Beverly K.	MGC
Wiley, Ericka N.	OS SHIFT LEAD
William, Darien J.	OPR TECH I
Williams, Britney A.	503B OPS LEAD TCH
Williams, Carrie L.	ASST COMP ASMBLY MGR
Williams, Cedrick T.	STRL RM TECH I
Williams, Chamara R.	CLN RM QA TIER I
Williams, Darius R.	DOC CNTRL SPC I
Williams, Joy S.	QO PMPK SPRV
Williams, Mervin L.	SR RD FORM SCI
Williams, Morgan S.	503B OPS LEAD TCH
Williamson, Colby J.	QC MICRO MGR
Williamson, Richard B.	503B OPS SUP
Willis, Vincent R.	STRL RM TECH I
Willm, Robert D.	SNR BUS OPS MGR
Wilson, DeKira	FRM TECH I
Wilson, Zoey U.	STRL RM TECH I
Windom, Terrill	STRL RM TECH I
Winfield, James E.	SEC OFCR
Winkler, Alex N.	STBL OP TECH I
Wolfram, David R.	UTL MNT TECH
Wood, Daniel P.	FRM EQP SP
Wood, Jared T.	SNR AUTO SRV MGR
Woods, Matthew B.	FORMMGMT
Wright, Frankie V.	BFS MAINT TCH II
Wright, ShaDonia	BFS LN TECH I
Wylie, Quintin A.	SEC PKG LEAD LINE TE
Wylie, Stephanie L.	QO SCPK Tier III
Yang, Faith N.	MICRO QLTY INVST
Yang, Zhengguan	SR RD FORM SCI
Yosurack, Carley L.	TERR SLS MGR
Young, Robert B.	CNC MACHIN
Zacharias, Christopher J.	RD CHEM III

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

MEMORANDUM

BOARD/PROGRAM	State Board of Pharmacy		
INVESTIGATOR	Lisa Cornett		
CASE NUMBER		DATE OF MEMORANDUM	10/27/22

RESPONDENT INFORMATION	
Name	Nephron SC Inc.

LICENSE TYPE	LICENSE #	STATUS	FIRST ISSUED	EXPIRATION	METHOD
WHO	8233	Active	2/10/17	10/31/24	Original

RESPONDENT ATTORNEY	None noted.

COMPLAINANT INITIALS	State Board of Pharmacy
FACILITY	

SUMMARY

The State Board of Pharmacy was notified of a "Warning Letter" that was issued by the Food and Drug Administration (FDA) on 10/11/22 to Nephron SC, Inc., 4500 12th Street Ext, West Columbia, SC 29172 (Attachment 1).

The "Warning Letter" details, among other things the following:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Nephron SC Inc., FEI 3010892830, at 4500 12th Street Ext., West Columbia, SC from March 28 to April 20, 2022.
This warning letter summarizes significant violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations (CFR), parts 210 and 211 (21 CFR parts 210 and 211).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&CAct), 21 U.S.C. 351(a)(2)(B).

In addition, the inspection revealed that your firm failed to submit an NDA Field Alert Report to FDA within three working days of receipt of information concerning significant chemical, physical, or other change or deterioration in a distributed drug product, as required by section 505(k) of the FD&C Act, 21 U.S.C. § 355(k) and stipulated by the regulation 21 C.F.R.§314.81(b)(1)(ii).

1. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR211.192).

Your firm failed to conduct adequate and timely investigations relating to products made by both terminal sterilization and aseptic processing.

Cross Contamination

Your firm manufactures products that undergo moist heat sterilization, including Sterile Water for Injection, USP, Ketorolac Tromethamine Injection, USP, 60 mg/ 2 mL, Sodium Chloride Injection 0.9%, USP, as well as pending application products undergoing development studies.

Your firm's testing found cross contamination of drugs in at least three lots of drug products. You failed to adequately identify the root cause or scope of potentially impacted lots in a timely manner.
Your investigation was initiated on April 2, 2021, when you detected the presence of the drug Bupivacaine, produced from your outsourcing facility (under section 503B FD&C Act), in a lot of drug product pending application approval, (b)(4). You attributed the root cause to a combination of the nature of terminal sterilization cycles and the permeability of the container closure system (CCS) used to produce your drug products.

It is essential that your firm does not introduce risks through overlap of your outsourcing and conventional production operations by sharing equipment, facilities, processes, or personnel, as the applicable standards significantly differ in certain respects. The attempt to mix these operations and follow two different standards increases complexity and product hazards. Notably, your firm uses common equipment, including blow-fill-seal (BFS) machines and your sterilizing equipment, for 503B compounding operations as well as conventional drug manufacturing operations. You found flaws in your IV bag CCS, including high permeability in the CCS that allows for contamination of the autoclave and infiltration into the containers (e.g., LDPE vials and IV bags) of subsequent batches of drug products produced in the common sterilization equipment.

A phase two investigation related to the cross-contamination was opened on April 30, 2021, and remained open at the time of the inspection, which was initiated on March 28, 2022. Our inspection found that you continued to manufacture drug products with the same CCS and autoclave cycles. Only after FDA's inspection did you perform additional investigation and CAPA. Your lack of a timely and comprehensive investigation failed to identify the extent of the cross-contamination hazard to marketed drug products.

In your response, you provide an updated investigation. It extends the evaluation to other drug products using the same CCS and includes limited studies within the sterilizing equipment and limited testing for cross-contamination of potentially affected drug products.

Your response is inadequate. Your investigation does not consider other sources of contamination. With only limited data, you conclude that the measured level of cross-contamination was "negligible." Furthermore, you indicate that the identified corrective action of running (b)(4) autoclave cycles between products to "clean" this equipment found "a statistically significant reduction in carry-over." However, your investigation does not adequately consider flaws related to your CCS (including, but not limited to, material quality and compatibility with the manufacturing process), and determine whether it provides suitable protection against egress and ingress of cross-contaminants. Your response lacks a commitment

to review your CCS for raw material quality and vendor reliability. This concern not only relates to your current drug products but also your pending application drug products.
You also do not sufficiently address other potential root causes, such as a leak due to a CCS breach, that could be a potential source of cross-contamination within an autoclave. In addition, your investigation does not fully consider the impact of container-closure permeability on sterility assurance or product potency.

Contamination is generally nonuniformly distributed as your own data indicates. The test data in your investigation is limited to a small number of units, and the extent of contaminated units in a batch remains unknown. The number of contaminated units and degree of contamination may far exceed levels identified by your firm. Your study with limited testing shows cross-contamination of Bupivacaine active in Sterile Water for Injection with a wide range of variability of contamination levels (i.e., a four-fold range). However, you conclude that the cross-contamination between medicines is uniform and not at a sufficient level of concern.

Your firm does not consider that the highest result in the range from a very small sample is unlikely to reveal the highest contamination level in a batch. Furthermore, for the drug products tested and reported with results of "not detected," you assume that the result is representative of the entire lot. Testing of your retain samples alone is insufficient to determine the scope of the contamination issues and mitigate risks associated with the contamination. You also state, "The data were assessed within alignment of ICH Q3B impurity thresholds" and "Impurities analysis is governed by ICH Q3B wherein thresholds are set to dictate the level of concern and identification required for impurities." This is an inappropriate interpretation of the ICH Q3B guideline, as it applies to impurities classified as degradation products and excludes extraneous contaminants.

You continued to observe cross-contamination in your drug products without adequately evaluating the scope of impacted lots nearly a year after you initially identified the contamination. On May 27, 2022, approximately a year after the investigation was initiated, you submitted Field Alert Reports (FARs).

On August 2, 2022, FDA held a teleconference with you about your contaminated drugs. On August 10, 2022, you conducted a voluntary recall of lot 023011 of Ketorolac Tromethamine Injection, USP, 60 mg/ 2 mL (and 4 lots of products made as part of your outsourcing operation), as noted on the following FDA website:
https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=195477.

Microbial Contamination

Your investigation into process simulation (media fill) failures was inadequate as you failed to implement appropriate CAPA to prevent microbial contamination. Your firm experienced two media fill failures, in which Pseudomonas aeruginosa (gram-negative rods) was detected in your BFS mandrel cooling water. It is highly atypical to have gram-negative microbes in the aseptic production cleanroom environment or identified in a media fill. For example, media fill lot M02801 identified Pseudomonasaeruginosa in a large number of turbid units ((b)(4)). You conducted a single repeat media fill to requalify the BFS for production after repairing the water leak from the mandrel, and cleaning and disinfecting the outer surfaces of the BFS. A single media fill is insufficient to support the requalification of your aseptic operations. In this situation, a comprehensive CAPA should be implemented followed by three successful and consecutive runs to requalify your aseptic process after a media fill failure.

You also detected this organism elsewhere in your operation including routine environmental monitoring (EM) and water samples.

For example, following the maintenance of your water for injection (WFI) system on June 4 and June 5, 2020, you identified several instances of Pseudomonas aeruginosa and other species including seven samples that yielded too-numerous-to-count (TNTC) CFU/100mL results. investigation attributed the results to laboratory error, due to a presumed contaminated (b)(4), and invalidated the results without clear evidence establishing laboratory error as the cause. You also based your investigation conclusion on other test results from batches formulated between June 4 to 6, 2020, that did not "recover" Pseudomonas aeruginosa and indicate that drug product testing on June 21, 2020, identified Pseudomonas spp. using the vacuum manifold. You did not confirm the source of the contamination and your CAPA was limited to retraining your microbiology laboratory personnel. Notably, you identified no CAPA for the autoclaving of the (b)(4). Your SOP requires the (b)(4) to be autoclaved (b)(4) but you failed to follow your SOP, determine why the step was not documented and caught in time, and explain how you will be improving your laboratory system to prevent similar future errors.

Your minimal retrospective review of batch data for the presence of Pseudomonas spp. is also inadequate. The presence of highly pathogenic microorganisms in your environment can present severe risks that can be potentially fatal to patients. Their presence should receive urgent and effective remediation. It should also be noted that finished product testing alone cannot establish(https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=195477) sterility of all units because contamination is typically episodic and not uniformly distributed. Larger contamination problems may go undetected for substantial periods if your firm is placing too much reliance on the final quality control test for sterility to become aware of a problem in aseptic manufacturing.
In your response, you commit to flush the BFS cooling water reservoirs (b)(4) to reduce bioburden to limit the potential for biofilm formation, establish a clean-in-place (CIP) program for the cooling water systems, and conduct trending to determine the optimal flush frequency. Your response also includes a preventative maintenance procedure for your BFS machine that requires a pre-check to inspect for the presence of moisture in the (b)(4). Relying on visual inspection of (b)(4) to detect the presence of moisture is insufficient to prevent the ingress of mandrel cooling water into your BFS filler and will not robustly prevent contamination of sterile medicines made by your firm. Your response is inadequate because you did not review the fundamental design and integrity of your BFS machinery (including, but not limited to, the suitability of the BFS cooling system for its intended use).

2. Your firm failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes (21 CFR 211.113(b)).

You did not establish appropriate environmental monitoring (EM) action levels for the ISO 5 critical area where drugs are most vulnerable to contamination. Samples from the ISO 5 critical area should normally yield no microbiological contaminants. Because of the inappropriate action level, you failed to investigate three of six ISO viable EM samples that were > 1 CFU in your BFS lines. Appropriate ISO 5 action levels are a critical part of a robust EM program to prevent microbiological contamination of sterile drug products.

In your response, you state that you have revised your ISO 5 action levels for air, surface, and some personnel monitoring (PM) to(b)(4) CFU/plate. You also state that you investigated microbiological contamination from air sampling within the ISO 5 critical areas that exceeded the action level and conclude that the contamination "posed no negative risk" to the sterility assurance of the lots. However, your response is inadequate because you did not conduct a comprehensive retrospective assessment of historical EM data for actionable events and you failed to provide an assessment of your established EM and PM alert and action levels (e.g., settling plates, chest, head, goggles, forearms) to assure your levels are appropriate to monitor your manufacturing environment.

We also note that your firm has been applying the ISO 5 action level for active air monitoring from USP <797> (Pharmaceutical Compounding - Sterile Preparations) to your sterile drug production operation. USP < 797> is not an appropriate regulatory standard for your operations. If your firm continues to conduct outsourcing activities and conventional drug manufacturing operations at the same site, the higher CGMP standard needs to be followed in the event there are any overlapping (where appropriate) activities. While overlapping activities should be avoided, if any common facilities, personnel and equipment are used, they must be designed, maintained, and controlled in compliance with the standards for conventional manufacturing under the CGMPs for finished pharmaceuticals, 21 CFR 210 and 211. Otherwise, you should fully separate your operations.

3. Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(c)(10)(iv)).

Sampling of the BFS machines in your EM program for ISO 5 active air viable and non-viable monitoring is deficient. You failed to demonstrate that the method used for sample collection for EM (e.g., use of tubing with a length of about (b)(4) and material) provides a meaningful and representative sample of conditions during production. The air sample tubing was held between the door jamb and the door to your BFS, potentially disrupting the air flow to your sampling instruments. Furthermore, your established procedure fails to adequately describe the configuration of the tubing used to monitor viable and non-viable samples to address the potential of compromised airflow within the tubing.
In your response, you provide rationale for the sampling procedure and agree that the sampling should be collected as close to the point of fill as possible without impacting the airflow within the blow fill seal machine environment. In addition, your response includes the manufacturer's recommendation that tubing is free of bends with a radius of less than (b)(4) to minimize the loss of larger particles by impaction and prevents the possibility of tubing collapse.

Your response is inadequate because, you did not provide supportive studies evaluating whether your sampling method is capable of adequality monitoring your ISO 5 environment as intended. You did not revise your procedures to establish the proper configuration of your tubing to assure the airflow path is not impeded. Furthermore, EM instruments should be located and placed in an orientation demonstrated to obtain a meaningful sample.

The aforementioned violations may be considered violations of Colorado Statute 12-280-126. Unprofessional conduct - grounds for discipline. (1) The board may take disciplinary or other action as authorized in section 12-20-404, after a hearing held in accordance with the provisions of sections 12-20-403 and 12-280-127, upon proof that the licensee, certificant, or registrant: (c) has violated: (III) Any state or federal law pertaining to drugs.

ATTACHMENTS	EXHIBITS
1. "Warning Letter"	1.
2.	2.

CRL

Reviewer's Initials

WARNING LETTER

Nephron SC Inc.

MARCS-CMS 634647 – OCTOBER 11, 2022

Delivery Method:

VIA Electronic Mail

Product:

Drugs

Recipient:

Ms. Lou W. Kennedy

Chief Executive Officer and Owner

Nephron SC Inc.

4500 12th Street Ext.
West Columbia, SC 29172
United States

lkennedy@nephronpharm.com (mailto:lkennedy@nephronpharm.com)

Issuing Office:

Office of Pharmaceutical Quality Operations, Division II

United States

October 11, 2022

Case # 634647

WARNING LETTER

Dear Ms. Kennedy:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Nephron SC Inc., FEI 3010892830, at 4500 12th Street Ext., West Columbia, SC from March 28 to April 20, 2022.

This warning letter summarizes significant violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations (CFR), parts 210 and 211 (21 CFR parts 210 and 211).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

In addition, the inspection revealed that your firm failed to submit an NDA Field Alert Report to FDA within three working days of receipt of information concerning significant chemical, physical, or other change or deterioration in a distributed drug product, as required by section 505(k) of the FD&C Act, 21 U.S.C. § 355(k) and stipulated by the regulation 21 C.F.R.§314.81(b)(1)(ii).

We reviewed your May 11, 2022, response to our Form FDA 483 in detail and acknowledge receipt of your subsequent correspondence.

During our inspection, our investigators observed specific violations including, but not limited to, the following.

1. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192).

Your firm failed to conduct adequate and timely investigations relating to products made by both terminal sterilization and aseptic processing.

Cross Contamination

Your firm manufactures products that undergo moist heat sterilization, including Sterile Water for Injection, USP, Ketorolac Tromethamine Injection, USP, 60 mg/ 2 mL, Sodium Chloride Injection 0.9%, USP, as well as pending application products undergoing development studies.

Your firm's testing found cross contamination of drugs in at least three lots of drug products. You failed to adequately identify the root cause or scope of potentially impacted lots in a timely manner.

Your investigation was initiated on April 2, 2021, when you detected the presence of the drug Bupivacaine, produced from your outsourcing facility (under section 503B FD&C Act), in a lot of drug product pending application approval, **(b)(4)**. You attributed the root cause to a combination of the nature of terminal sterilization cycles and the permeability of the container closure system (CCS) used to produce your drug products.

It is essential that your firm does not introduce risks through overlap of your outsourcing and conventional production operations by sharing equipment, facilities, processes, or personnel, as the applicable standards significantly differ in certain respects. The attempt to mix these operations and follow two different standards increases complexity and product hazards. Notably, your firm uses common equipment, including blow-fill-seal (BFS) machines and your sterilizing equipment, for 503B compounding operations as well as conventional drug manufacturing operations. You found flaws in your IV bag CCS, including high permeability in the CCS that allows for contamination of the autoclave and infiltration into the containers (e.g., LDPE vials and IV bags) of subsequent batches of drug products produced in the common sterilization equipment.

A phase two investigation related to the cross-contamination was opened on April 30, 2021, and remained open at the time of the inspection, which was initiated on March 28, 2022. Our inspection found that you continued to manufacture drug products with the same CCS and autoclave cycles. Only after FDA's inspection did you perform additional investigation and CAPA. Your lack of a timely and comprehensive investigation failed to identify the extent of the cross-contamination hazard to marketed drug products.

In your response, you provide an updated investigation. It extends the evaluation to other drug products using the same CCS, and includes limited studies within the sterilizing equipment and limited testing for cross-contamination of potentially affected drug products.

Your response is inadequate. Your investigation does not consider other sources of contamination. With only limited data, you conclude that the measured level of cross-contamination was "negligible." Furthermore, you indicate that the identified corrective action of running **(b)(4)** autoclave cycles between products to "clean" this equipment found "a statistically significant reduction in carry-over." However, your investigation does not adequately consider flaws related to your CCS (including, but not limited to, material quality and compatibility with the manufacturing process), and determine whether it provides suitable protection against egress and ingress of cross-contaminants. Your response lacks a commitment to review your CCS for raw material quality and vendor reliability. This concern not only relates to your current drug products but also your pending application drug products.

You also do not sufficiently address other potential root causes, such as a leak due to a CCS breach, that could be a potential source of cross-contamination within an autoclave. In addition, your investigation does not fully consider the impact of container-closure permeability on sterility assurance or product potency.

Contamination is generally nonuniformly distributed as your own data indicates. The test data in your investigation is limited to a small number of units, and the extent of contaminated units in a batch remains unknown. The number of contaminated units and degree of contamination may far exceed levels identified by your firm. Your study with limited testing shows cross-contamination of Bupivacaine active in Sterile Water for Injection with a wide range of variability of contamination levels (i.e., a four-fold range). However, you conclude that the cross-contamination between medicines is uniform and not at a sufficient level of concern.

Your firm does not consider that the highest result in the range from a very small sample is unlikely to reveal the highest contamination level in a batch. Furthermore, for the drug products tested and reported with results of "not detected," you assume that the result is representative of the entire lot. Testing of your retain samples alone is insufficient to determine the scope of the contamination issues and mitigate risks associated with the contamination. You also state, "The data were assessed within alignment of ICH Q3B impurity thresholds" and "Impurities analysis is governed by ICH Q3B wherein thresholds are set to dictate the level of concern and identification required for impurities." This is an inappropriate interpretation of the ICH Q3B' guideline, as it applies to impurities classified as degradation products and excludes extraneous contaminants.

You continued to observe cross-contamination in your drug products without adequately evaluating the scope of impacted lots nearly a year after you initially identified the contamination. On May 27, 2022, approximately a year after the investigation was initiated, you submitted Field Alert Reports (FARs).

On August 2, 2022, FDA held a teleconference with you about your contaminated drugs. On August 10, 2022, you conducted a voluntary recall of lot 023011 of Ketorolac Tromethamine Injection, USP, 60 mg/ 2 mL (and 4 lots of products made as part of your outsourcing operation), as noted on the following FDA website: https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=195477 (https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=195477)

Microbial Contamination

Your investigation into process simulation (media fill) failures was inadequate as you failed to implement appropriate CAPA to prevent microbial contamination. Your firm experienced two media fill failures, in which *Pseudomonas aeruginosa* (gram-negative rods) was detected in your BFS mandrel cooling water. It is highly atypical to have gram-negative microbes in the aseptic production cleanroom environment or identified in a media fill. For example, media fill lot M02801 identified *Pseudomonas aeruginosa* in a large number of turbid units (**(b)(4)**). You conducted a single repeat media fill to requalify the BFS for production after repairing the water leak from the mandrel, and cleaning and disinfecting the outer surfaces of the BFS. A single media fill is insufficient to support the requalification of your aseptic operations. In this situation, a comprehensive CAPA should be implemented followed by three successful and consecutive runs to requalify your aseptic process after a media fill failure.

You also detected this organism elsewhere in your operation including routine environmental monitoring (EM) and water samples.

For example, following the maintenance of your water for injection (WFI) system on June 4 and June 5, 2020, you identified several instances of *Pseudomonas aeruginosa* and other species including seven samples that yielded too-numerous-to-count (TNTC) CFU/100mL results. Your investigation attributed the results to laboratory error, due to a presumed contaminated **(b)(4)**, and invalidated the results without clear evidence establishing laboratory error as the cause. You also based your investigation conclusion on other test results from batches formulated between June 4 to 6, 2020, that did not "recover" *Pseudomonas aeruginosa* and indicate that drug product testing on June 21, 2020, identified *Pseudomonas spp.* using the vacuum manifold. You did not confirm the source of the contamination and your CAPA was limited to retraining your microbiology laboratory personnel. Notably, you identified no CAPA for the autoclaving of the **(b)(4)**. Your SOP requires the **(b)(4)** to be autoclaved **(b)(4)** but you failed to follow your SOP, determine why the step was not documented and caught in time, and explain how you will be improving your laboratory system to prevent similar future errors.

Your minimal retrospective review of batch data for the presence of Pseudomonas spp. is also inadequate. The presence of highly pathogenic microorganisms in your environment can present severe risks that can be potentially fatal to patients. Their presence should receive urgent and effective remediation. It should also be noted that finished product testing alone cannot establish

sterility of all units because contamination is typically episodic and not uniformly distributed. Larger contamination problems may go undetected for substantial periods if your firm is placing too much reliance on the final quality control test for sterility to become aware of a problem in aseptic manufacturing.

In your response, you commit to flush the BFS cooling water reservoirs **(b)(4)** to reduce bioburden to limit the potential for biofilm formation, establish a clean-in-place (CIP) program for the cooling water systems, and conduct trending to determine the optimal flush frequency. Your response also includes a preventative maintenance procedure for your BFS machine that requires a pre-check to inspect for the presence of moisture in the **(b)(4)**. Relying on visual inspection of **(b)(4)** to detect the presence of moisture is insufficient to prevent the ingress of mandrel cooling water into your BFS filler, and will not robustly prevent contamination of sterile medicines made by your firm. Your response is inadequate because you did not review the fundamental design and integrity of your BFS machinery (including, but not limited to, the suitability of the BFS cooling system for its intended use).

In response to this letter, provide:

- A comprehensive, independent assessment of your overall system for investigating deviations, discrepancies, complaints, OOS results, and failures. Provide a detailed action plan to remediate this system. Your action plan should include, but not be limited to, significant improvements in investigation competencies, scope determination, root cause evaluation, CAPA effectiveness, quality assurance oversight, and written procedures. Address how your firm will ensure all phases of investigations are appropriately conducted. An independent assessment and remediation plan for your CAPA program. Provide a report that evaluates whether the program includes effective root cause analysis, ensures CAPA effectiveness, analyzes investigations trends, improves the CAPA program when needed, implements final quality assurance decisions, and is fully supported by executive management.
- A procedure for your water system monitoring that provides for appropriate daily microbial testing of water to ensure its acceptability for use in each lot of drug products produced by your firm.
- A procedure governing your program for ongoing control, maintenance, and monitoring that ensures the system consistently produces water that meets Purified Water, USP, and WFI USP, monograph specifications and appropriate microbial limits.
- In addition to this holistic remediation, provide specific CAPA activities that are being undertaken to effectively remediate the conditions that caused the specific cross-contamination incidents discussed above. Provide an independent review by your consultant that determines the effectiveness of your CAPA, including but not limited to:

o A list of all enhancements to cleaning and maintenance procedures including specific frequencies and locations to be cleaned in all relevant equipment

o Identify any other sources of cross contamination other than the sterilizing equipment

o Determine the adequacy of your analytical methodology to identify residual carryover

o Supporting evidence to demonstrate that the challenges identified during your study, such as interference of product matrix and co-eluting peaks, were adequately resolved

o Adequacy of scope of the investigation and its related CAPA

- The latest update on your improvements to your cleaning validation program, with special emphasis on incorporating conditions identified as worst case in your drug manufacturing operation. This should include, but not be limited to, identification and evaluation of all worst-case:

o Drugs with higher toxicities

o Drugs with higher drug potencies

o Drugs of lower solubility in their cleaning solvents

o Drugs with characteristics that make them difficult to clean

o Swabbing locations for areas that are most difficult to clean

o Maximum hold times before cleaning

In addition, describe the steps that must be taken in your change management system before introduction of a new drug product or new manufacturing equipment.

- A commitment to conduct testing between lots of autoclaved drug products using sensitive testing techniques such as liquid chromatography mass spectrophotometry (LCMS) prior to release to determine whether there is any cross contamination with your mixed operations.
- An independent assessment to include, but not limited to, the suitability of material composition, reliability of suppliers, fabrication process, and all other factors that influence the CCS quality and integrity. The assessment should evaluate all aspects of CCS suitability including its permeability and ability to provide protection from external factors affecting the sterility assurance or potency of batches of products manufactured in an autoclave or other sterilizing equipment.
- An independent, comprehensive review of the adequacy of design, control, and maintenance of your BFS machinery. When describing the maintenance program, provide all failure modes of water ingress that can occur, a description and the

purpose of the **(b)(4)** in your BFS mandrel design. Based on this comprehensive review, provide a CAPA to prevent recurrence of BFS system contamination with water-borne gram-negative microbes.

2. Your firm failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes (21 CFR 211.113(b)).

You did not establish appropriate environmental monitoring (EM) action levels for the ISO 5 critical area where drugs are most vulnerable to contamination. Samples from the ISO 5 critical area should normally yield no microbiological contaminants. Because of the inappropriate action level, you failed to investigate three of six ISO viable EM samples that were ≥ 1 CFU in your BFS lines. Appropriate ISO 5 action levels are a critical part of a robust EM program to prevent microbiological contamination of sterile drug products.

In your response, you state that you have revised your ISO 5 action levels for air, surface, and some personnel monitoring (PM) to **(b)(4)** CFU/plate. You also state that you investigated microbiological contamination from air sampling within the ISO 5 critical areas that exceeded the action level and conclude that the contamination "posed no negative risk" to the sterility assurance of the lots. However, your response is inadequate because you did not conduct a comprehensive retrospective assessment of historical EM data for actionable events and you failed to provide an assessment of your established EM and PM alert and action levels (e.g., settling plates, chest, head, goggles, forearms) to assure your levels are appropriate to monitor your manufacturing environment.

We also note that your firm has been applying the ISO 5 action level for active air monitoring from USP <797> (Pharmaceutical Compounding – Sterile Preparations) to your sterile drug production operation. USP < 797> is not an appropriate regulatory standard for your operations. If your firm continues to conduct outsourcing activities and conventional drug manufacturing operations at the same site, the higher CGMP standard needs to be followed in the event there are any overlapping (where appropriate) activities. While overlapping activities should be avoided, if any common facilities, personnel and equipment are used, they must be designed, maintained, and controlled in compliance with the standards for conventional manufacturing under the CGMPs for finished pharmaceuticals, 21 CFR 210 and 211. Otherwise, you should fully separate your operations.

See FDA's guidance document Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice to help you meet the CGMP requirements for establishing appropriate EM and PM action levels when manufacturing sterile drugs using aseptic processing at https://www.fda.gov/media/71026/download (https://www.fda.gov/media/71026/download).

In response to this letter, provide:

- Comprehensive risk assessment of all contamination hazards with respect to your aseptic processes, equipment, and facilities, including an independent assessment that includes, but is not limited to:

o All human interactions within the ISO 5 area
o Equipment placement and ergonomics
o Air quality in the ISO 5 area and surrounding room
o Facility layout
o Personnel Flows and Material Flows (throughout all rooms used to conduct and support sterile operations)

- A detailed remediation plan with timelines to address the findings of the contamination hazards risk assessment. Describe specific tangible improvements to be made to aseptic processing operation design and control.
- Your investigations into all environmental data that reached alert and action levels for the past two years.
- Your plan to review and ensure EM/PM alert levels, action levels, procedures, and CAPA are robust and appropriate.

3. Your firm failed to establish an adequate system for monitoring environmental conditions in aseptic processing areas (21 CFR 211.42(c)(10)(iv)).

Sampling of the BFS machines in your EM program for ISO 5 active air viable and non-viable monitoring is deficient. You failed to demonstrate that the method used for sample collection for EM (e.g., use of tubing with a length of about **(b)(4)** and material) provides a meaningful and representative sample of conditions during production. The air sample tubing was held between the door jamb and the door to your BFS, potentially disrupting the air flow to your sampling instruments. Furthermore, your established procedure fails to adequately describe the configuration of the tubing used to monitor viable and non-viable samples to address the potential of compromised airflow within the tubing.

In your response, you provide rationale for the sampling procedure and agree that the sampling should be collected as close to the point of fill as possible without impacting the airflow within the blow fill seal machine environment. In addition, your response includes the manufacturer's recommendation that tubing is free of bends with a radius of less than **(b)(4)** to minimize the loss of larger particles by impaction and prevents the possibility of tubing collapse.

Your response is inadequate because, you did not provide supportive studies evaluating whether your sampling method is capable of adequality monitoring your ISO 5 environment as intended. You did not revise your procedures to establish the proper configuration of your tubing to assure the airflow path is not impeded. Furthermore, EM instruments should be located and placed in an orientation demonstrated to obtain a meaningful sample.

In response to this letter, provide:

- A thorough, independent assessment, and CAPA for your EM and facility monitoring program. Include a comprehensive evaluation of monitoring, recording, alarm documentation, deviation investigation, data retention and overall environmental control in your assessment.
- Your CAPA plan to implement routine, vigilant operations management oversight of facilities and equipment. This plan should ensure, among other things, prompt detection of equipment/facilities performance issues, effective execution of repairs, adherence to appropriate preventive maintenance schedules, timely technological upgrades to the equipment/facility infrastructure, and improved systems for ongoing management review.
- The actual length of the EM sampling tubing and the distance from the sampling location to the point of fill on your BFS with supporting photographs.
- Studies evaluating whether your program for viable and non-viable EM operates as intended with the configurations you have established.
- Revised procedures that assure EM sampling tubing configuration is suitable for collecting reliable environmental data.

Additional Guidance on Aseptic Processing

See FDA's guidance document *Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice* to help you meet the CGMP requirements when manufacturing sterile drugs using aseptic processing at https://www.fda.gov/media/71026/download (https://www.fda.gov/media/71026/download).

Recall and Temporary Suspension of Manufacturing

We acknowledge that you recalled lot 023011 of Ketorolac Tromethamine Injection, USP, 60 mg/ 2 mL drug product as well as four outsourcing facility compounding drug products after the FDA contacted you via telephone on August 2, 2022.

We acknowledge your commitment to temporarily suspend production of some drug products (terminally sterilized by moist heat) at this facility. You indicated that you planned to resume operations on August 23, 2022. Resumption of manufacturing your drugs terminally sterilized by moist heat should only occur once you have implemented effective CAPA and completed appropriate submission requirements.

CGMP Consultant Recommended

Based upon the nature of the violations we identified at your firm, you should engage a consultant qualified as set forth in 21 CFR 211.34 to assist your firm in meeting CGMP requirements. The qualified consultant should also perform a comprehensive audit of your entire operation for CGMP compliance and evaluate the completion and efficacy of all identified corrective actions and preventive actions before you pursue resolution of your firm's compliance status with FDA.

Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for resolving all deficiencies and systemic flaws to ensure ongoing CGMP compliance.

Field Alert Reporting Violations

The NDA/ANDA Field Alert reporting requirements in 21 CFR 314.81(b)(1)(i) and (ii), effective since May 23, 1985, require holders of NDAs and ANDAs to submit information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product to the appropriate FDA district office within three working days of receipt by the applicant. The intent of the 21 CFR 314.81(b)(1) regulation is to establish an early warning system so that significant problems are brought to the FDA's attention by applicant holders in order to prevent potential safety hazards from drug products already in distribution and also to prevent potential safety hazards with drug products manufactured in the future. FARs must be submitted for confirmed and unconfirmed problems meeting the definition of the regulation within three working days of becoming aware of the problem.

From this inspection, in addition to the aforementioned CGMP violations, your firm is in violation of the Field Alert reporting requirements set forth in 21 CFR 314.81(b)(1)(ii). Specifically, on April 2, 2021, you initiated an investigation into the out-of-trend results for stability samples at 6-months related to extractables and leachables for your pending ANDA for **(b)(4)**, USP 10mg/ml, that identified bupivacaine active in your drug product.

On May 27, 2022, you submitted three initial FARs for your approved ANDA products, Sterile Water for Injection, USP, Ketorolac Tromethamine Injection, USP, 60 mg/ 2 mL, and Sodium Chloride Injection 0.9%, USP, notifying the Agency that you were investigating the potential residual active ingredient carryover into manufactured lots for these drug products. The submission of these FARs is more than one year from your initial investigation identifying the potential carryover of drug active.

We are concerned with the CGMP violations demonstrated at your facility and failure to submit FAR-related events within three days of becoming aware of a problem. Please include in your written response the corrective action you plan to take regarding distributed products manufactured at your facility that may be affected by the violations.

Conclusion

The violations cited in this letter are not intended to be an all-inclusive list of violations exist at your facility. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations.

If you are considering an action that is likely to lead to a disruption in the supply of drugs produced at your facility, FDA requests that you contact CDER's Drug Shortages Staff immediately, at drugshortages@fda.hhs.gov, so that FDA can work with you on the most effective way to bring your operations into compliance with the law. Contacting the Drug Shortages Staff also allows you to meet any obligations you may have to report discontinuances or interruptions in your drug manufacture under 21 U.S.C. 356C(b). This also allows FDA to consider, as soon as possible, what actions, if any, may be needed to avoid shortages and protect the health of patients who depend on your products.

Correct any violations promptly. Failure to promptly and adequately address this matter may result in regulatory or legal action without further notice including, without limitation, seizure and injunction. Unresolved violations may also prevent other Federal agencies from awarding contracts.

Failure to address violations also cause FDA to withhold issuance of Export Certificates. FDA may withhold approval of new applications or supplements listing your firm as a drug manufacturer until any violations are completely addressed and we confirm your compliance with CGMP. We may re-inspect to verify that you have completed corrective actions to address any violations.

This letter notifies you of our findings and provides you an opportunity to address the above deficiencies. After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done to address any violations and to prevent their recurrence. In response to this letter, you may provide additional information for our consideration as we continue to assess your activities and practices. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Please electronically submit your reply on company letterhead to Mark W. Rivero, Compliance Officer, at ORAPHARM2_RESPONSES@fda.hhs.gov. In addition, please submit a signed copy of your response to Mr. Rivero.

If you have questions regarding the contents of this letter, you may contact Mr. Rivero via (954) 527-4239 or mark.rivero@fda.hhs.gov.

Sincerely,
/S/

Frances de Jesus
Acting Program Division Director
Office of Pharmaceutical Quality Operations,
Division II

---

1 Guidance for Industry Q3B(R2) Impurities in New Drug Products is available at: https://www.fda.gov/media/71733/download (https://www.fda.gov/media/71733/download)

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

January 20, 2023

Nephron SC, Inc.
Attn: Designated Representative
4500 12th Street Ext
West Columbia, SC 29172-3025

Sent via email to: license@nephronpharm.com

Re: License Number: WHO.8233
Case Number: 2022-8142

Dear Designated Representative,

The State Board of Pharmacy ("Board") has concluded its inquiry into the aforementioned matter. It was the Board's decision not to commence with formal proceedings against your professional license. However, the Board did determine disciplinary action in the form of this letter of admonition is warranted, pursuant to section 12-280-127(6), C.R.S.

Failure to comply with current Good Manufacturing Practices violates section 12-280-126(1)(c)(I) and (III), C.R.S.

By this letter, the Board takes the formal disciplinary action of admonishing you for the conduct specified above, and warns you that repetition of such practice may lead to imposition of more severe disciplinary action. This letter is an open public record and a reportable action to individuals or entities requesting disciplinary information. The Board strongly encourages you to review and understand the Pharmacists, Pharmacy Business, and Pharmaceuticals Practice Act requirements and obligations for the practice of pharmacy or as a pharmacy technician in Colorado.

In accordance with section 12-20-404(4), C.R.S., the Board advises you that you have the right to make a written request that the Board initiate formal disciplinary proceedings in order to adjudicate the conduct or acts upon which this letter is based. You must make your written request within twenty (20) days after receipt of this letter and address your request to Dmitry Kunin, Program Director, at the address listed below. If you make a timely request, the Board will deem this letter of admonition vacated and may proceed with disciplinary and/or injunctive proceedings in accordance with section 12-20-404(4)(b)(II), C.R.S., and applicable rules.

A Letter of Admonition, when accepted, becomes a permanent, public portion of your record. It is not, however, a restriction on your practice as a professional pharmacist or pharmacy technician.

If you have further questions or concerns, please visit our website at https://www.colorado.gov/dora/dpo or you can contact our office at dora_pharmacyboard@state.co.us or by calling (303) 894-7800.

Sincerely,

FOR THE STATE BOARD OF PHARMACY

Dmitry Kunin
Senior Program Director

cc:

Please complete a short survey at https://www.surveymonkey.com/r/B5JR27T regarding aspects of the service you received. Your anonymous response will be used to evaluate the service experience and to identify areas where improvements may be appropriate.

CERTIFICATE OF SERVICE

This is to certify that I have duly served the enclosed LETTER OF ADMONITION upon all parties herein by depositing copies of the same in the United States mail via USPS mail, at Denver, Colorado, or electronic mail this 20th day of January, 2023, addressed as follows:

Nephron SC, Inc.
Attn: Designated Representative
4500 12th Street Ext
West Columbia, SC 29172-3025

Sent via email to: license@nephronpharm.com

Lana Hyatte
Board Staff

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of Nephron SC, Inc. License Number NO00036 Expiration 12.31.25	Docket Number PHA-2022-0207 (CAS-2022-1376)

CONSENT AGREEMENT FOR REPRIMAND

The Massachusetts Board of Registration in Pharmacy (Board) and Nephron SC, Inc. (Pharmacy), a pharmacy licensed by the Board, license number NO00036, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the Pharmacy's record maintained by the Board:

1. The Pharmacy acknowledges the Board opened a Complaint against its Massachusetts pharmacy license related to the conduct set forth in Paragraph 2 below, identified as Docket Number PHA-2022-0207 (Complaint).

2. The Pharmacy and the Board agree to resolve this Complaint without making any admissions or findings and without proceeding to a formal adjudicatory hearing. The Complaint alleges the following:

   The Pharmacy was issued a Warning Letter by the United States Food and Drug Administration (FDA) for violations of standards of pharmacy practice. Consequently, the Board may take disciplinary action against the Pharmacy pursuant to Title 247 of the Code of Massachusetts Regulations (CMR) Section 10.03(1).

3. The Board and Pharmacy acknowledge and agree that based upon the information described in Paragraph 2 above, the Board could find the Pharmacy in violation of 247 CMR Section 10.03(1)(v) for committing one or more acts that violate recognized standards of pharmacy practice.

4. The Pharmacy agrees that the Board shall impose a REPRIMAND on its license based on the facts described in Paragraph 2 above, effective as of the date on which the Board signs this Agreement (Effective Date).

5. The Board agrees that in return for the Pharmacy's execution and successful compliance with all the requirements of this Agreement, the Board will not prosecute the Complaint.

6. The Pharmacy understands that it has a right to formal adjudicatory hearing concerning the Complaint and that during said adjudication the Pharmacy would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to testify on its own behalf, to contest the allegations, to present oral argument, to appeal to the courts, and all other rights as set forth in the Massachusetts Administrative Procedures Act, MGL Chapter 30A, and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR § 1.01, *et seq.* The Pharmacy further understands that by executing this Agreement, the Pharmacy is knowingly and voluntarily waiving its right to a formal adjudication of the Complaint.

7. The Pharmacy acknowledges that it has been at all times represented by Counsel or otherwise free to seek and use legal counsel in connection with the Complaint and this Agreement.

8. The Pharmacy acknowledges that after the Effective Date, the Agreement constitutes a public record of disciplinary action by the Board subject to the Commonwealth of Massachusetts' Public Records Law, MGL Chapter 4, § 7. The Board may forward a copy of this Agreement to other licensing boards, law enforcement entities, and other individuals or entities as required or permitted by law.

9. The Pharmacy understands and agrees that entering into this Agreement is a voluntary and final act and not subject to reconsideration, appeal, or judicial review.

10. The individual signing this Agreement certifies that they are authorized to enter into this Agreement on behalf of the Pharmacy, and that they have read this Agreement.

08/21/24
Date

Nephron SC, Inc.
(signature)

Lou W. Kennedy
(print name)

David Sencabaugh
David Sencabaugh, R. Ph.
Executive Director
Board of Registration in Pharmacy

8//21/24
Effective Date of Reprimand Agreement

Fully Signed Agreement Sent to Licensee on 8 / 23 / 2024 by Certified Mail No. 7020 0090 0001 1042 2835

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

January 20, 2023

Nephron SC, Inc.
Attn: Designated Representative
4500 12th Street Ext
West Columbia, SC 29172-3025

Sent via email to: license@nephronpharm.com

Re: License Number: WHO.8233
Case Number: 2022-8142

Dear Designated Representative,

The State Board of Pharmacy ("Board") has concluded its inquiry into the aforementioned matter. It was the Board's decision not to commence with formal proceedings against your professional license. However, the Board did determine disciplinary action in the form of this letter of admonition is warranted, pursuant to section 12-280-127(6), C.R.S.

Failure to comply with current Good Manufacturing Practices violates section 12-280-126(1)(c)(I) and (III), C.R.S.

By this letter, the Board takes the formal disciplinary action of admonishing you for the conduct specified above, and warns you that repetition of such practice may lead to imposition of more severe disciplinary action. This letter is an open public record and a reportable action to individuals or entities requesting disciplinary information. The Board strongly encourages you to review and understand the Pharmacists, Pharmacy Business, and Pharmaceuticals Practice Act requirements and obligations for the practice of pharmacy or as a pharmacy technician in Colorado.

In accordance with section 12-20-404(4), C.R.S., the Board advises you that you have the right to make a written request that the Board initiate formal disciplinary proceedings in order to adjudicate the conduct or acts upon which this letter is based. You must make your written request within twenty (20) days after receipt of this letter and address your request to Dmitry Kunin, Program Director, at the address listed below. If you make a timely request, the Board will deem this letter of admonition vacated and may proceed with disciplinary and/or injunctive proceedings in accordance with section 12-20-404(4)(b)(II), C.R.S., and applicable rules.

A Letter of Admonition, when accepted, becomes a permanent, public portion of your record. It is not, however, a restriction on your practice as a professional pharmacist or pharmacy technician.

If you have further questions or concerns, please visit our website at https://www.colorado.gov/dora/dpo or you can contact our office at dora_pharmacyboard@state.co.us or by calling (303) 894-7800.

Sincerely,

FOR THE STATE BOARD OF PHARMACY

Dmitry Kunin
Senior Program Director

cc:

Please complete a short survey at https://www.surveymonkey.com/r/B5JR27T regarding aspects of the service you received. Your anonymous response will be used to evaluate the service experience and to identify areas where improvements may be appropriate.

CERTIFICATE OF SERVICE

This is to certify that I have duly served the enclosed LETTER OF ADMONITION upon all parties herein by depositing copies of the same in the United States mail via USPS mail, at Denver, Colorado, or electronic mail this 20th day of January, 2023, addressed as follows:

Nephron SC, Inc.
Attn: Designated Representative
4500 12th Street Ext
West Columbia, SC 29172-3025

Sent via email to: license@nephronpharm.com

Lana Hyatte
Board Staff

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of Nephron SC, Inc. License Number NO00036 Expiration 12.31.25	Docket Number PHA-2022-0207 (CAS-2022-1376)

CONSENT AGREEMENT FOR REPRIMAND

The Massachusetts Board of Registration in Pharmacy (Board) and Nephron SC, Inc. (Pharmacy), a pharmacy licensed by the Board, license number NO00036, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the Pharmacy's record maintained by the Board:

1. The Pharmacy acknowledges the Board opened a Complaint against its Massachusetts pharmacy license related to the conduct set forth in Paragraph 2 below, identified as Docket Number PHA-2022-0207 (Complaint).

2. The Pharmacy and the Board agree to resolve this Complaint without making any admissions or findings and without proceeding to a formal adjudicatory hearing. The Complaint alleges the following:

   The Pharmacy was issued a Warning Letter by the United States Food and Drug Administration (FDA) for violations of standards of pharmacy practice. Consequently, the Board may take disciplinary action against the Pharmacy pursuant to Title 247 of the Code of Massachusetts Regulations (CMR) Section 10.03(1).

3. The Board and Pharmacy acknowledge and agree that based upon the information described in Paragraph 2 above, the Board could find the Pharmacy in violation of 247 CMR Section 10.03(1)(v) for committing one or more acts that violate recognized standards of pharmacy practice.

4. The Pharmacy agrees that the Board shall impose a REPRIMAND on its license based on the facts described in Paragraph 2 above, effective as of the date on which the Board signs this Agreement (Effective Date).

5. The Board agrees that in return for the Pharmacy's execution and successful compliance with all the requirements of this Agreement, the Board will not prosecute the Complaint.

6. The Pharmacy understands that it has a right to formal adjudicatory hearing concerning the Complaint and that during said adjudication the Pharmacy would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to testify on its own behalf, to contest the allegations, to present oral argument, to appeal to the courts, and all other rights as set forth in the Massachusetts Administrative Procedures Act, MGL Chapter 30A, and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR § 1.01, *et seq.* The Pharmacy further understands that by executing this Agreement, the Pharmacy is knowingly and voluntarily waiving its right to a formal adjudication of the Complaint.

7. The Pharmacy acknowledges that it has been at all times represented by Counsel or otherwise free to seek and use legal counsel in connection with the Complaint and this Agreement.

8. The Pharmacy acknowledges that after the Effective Date, the Agreement constitutes a public record of disciplinary action by the Board subject to the Commonwealth of Massachusetts' Public Records Law, MGL Chapter 4, § 7. The Board may forward a copy of this Agreement to other licensing boards, law enforcement entities, and other individuals or entities as required or permitted by law.

9. The Pharmacy understands and agrees that entering into this Agreement is a voluntary and final act and not subject to reconsideration, appeal, or judicial review.

10. The individual signing this Agreement certifies that they are authorized to enter into this Agreement on behalf of the Pharmacy, and that they have read this Agreement.

08/21/24
Date

Nephron SC, Inc.
(signature)

Lou W. Kennedy
(print name)

David Sencabaugh
David Sencabaugh, R. Ph.
Executive Director
Board of Registration in Pharmacy

8//21/24
Effective Date of Reprimand Agreement

Fully Signed Agreement Sent to Licensee on 8 / 23 / 2024 by Certified Mail No. 7020 0090 0001 1042 2835

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025* FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lou Kennedy , CEO

FIRM NAME	STREET ADDRESS
Nephron Sc Inc	4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturing & 503B Outsourcing Facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and written.

503B Outsourcing Facility

[redacted]

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Saundrea A Munroe, Investigator Rose L Jean-Mary, Investigator Kellia N Hicks, Investigator Simone E Pitts, National Expert X [redacted]	8/22/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025* FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lou Kennedy , CEO

FIRM NAME	STREET ADDRESS
Nephron Sc Inc	4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
West Columbia, SC 29172-3025	Sterile Drug Manufacturing & 503B Outsourcing Facility

[redacted]

[redacted]

B. [redacted]

[redacted]

[redacted]

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Saundrea A Munroe, Investigator Rose L Jean-Mary, Investigator Kellia N Hicks, Investigator Simone E Pitts, National Expert X [redacted]	8/22/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025* FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lou Kennedy , CEO	
FIRM NAME Nephron Sc Inc	STREET ADDRESS 4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturing & 503B Outsourcing Facility

[redacted]

Sterile Drug Manufacturing & 503B Outsourcing Facility

C. Your firm's media fill program does not ensure simulations are representative of routine

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Saundrea A Munroe, Investigator Rose L Jean-Mary, Investigator Kellia N Hicks, Investigator Simone E Pitts, National Expert X [redacted]	8/22/2025

commercial operations or worst-case conditions.

1. Media fill protocols and executed records simulate critical interventions only "at least once" rather than at a representative number, type, complexity, and frequency justified by actual production history. This reduces the intervention load and fails to reflect worst-case conditions.

2. Routine production batch records do not consistently document the type, frequency, and timing of interventions, including non-routine/unplanned interventions, preventing data-driven justification of media fill design.

As designed and executed, the media fills do not provide adequate assurance of sterility for commercial operations, increasing the risk of undetected contamination during routine aseptic processing.

D. You have not demonstrated in your disinfectant efficacy study that your established contact time of two (2) minutes for sterile 70% isopropyl alcohol used as a disinfectant in your facility is capable of decontaminating nitrile surfaces. Nitrile gloves are primarily used for operating within the ISO-5 and ISO-7 cleanroom environments where sterile drug products are manufactured.

This is a repeated observation from the inspection performed 11/2023 – 02/2023, 01/29/2024 – 02/09/2024.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

AMENDMENT 1

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025*
	FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lou Kennedy , CEO	
FIRM NAME Nephron Sc Inc	STREET ADDRESS 4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturing & 503B Outsourcing Facility

503B Outsourcing Facility

Specifically,

[redacted]

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Saundrea A Munroe, Investigator Rose L Jean-Mary, Investigator Kellia N Hicks, Investigator Simone E Pitts, National Expert	8/22/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025* FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lou Kennedy , CEO

FIRM NAME	STREET ADDRESS
Nephron Sc Inc	4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
West Columbia, SC 29172-3025	Sterile Drug Manufacturing & 503B Outsourcing Facility

[redacted]

OBSERVATION 3

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

Sterile Drug Manufacturing & 503B Outsourcing Facility

1. You have failed to determine root cause and implement effective corrective action for cracked media plates used for environmental monitoring (EM) analysis. You first identified this issue on

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Saundrea A Munroe, Investigator Rose L Jean-Mary, Investigator Kellia N Hicks, Investigator Simone E Pitts, National Expert X	8/22/2025

02/14/2024, where it then became an on-going issue. In February 2025, you initiated and closed a Corrective Action/Preventative Action (CAPA) without determining the root cause. Since closure of the CAPA, you have generated approximately nine (9) additional cracked plate events. Additionally, during 02/14/2024 – 02/25/2025, you generated approximately 87 events where you discarded and invalidated damaged media samples without incubating them. Discarded media plates largely include personnel monitoring samples that were collected to document the environmental conditions for media fills and the production of sterile drug products.

This is a repeated observation from the inspection performed 01/29/2024 – 02/09/2024

2. You have not determined suitability of your EM sampling process of using settle plates as opposed to RODAC contact plates for performing personnel fingertip monitoring. This change was implemented on 05/14/2024 in response to the cracked/damaged media plates on-going issue that was identified 02/14/2024.

Sterile Drug Manufacturing

3. You inappropriately invalidated a stability sample at T_0 for sterility for Provocholine (methacholine chloride) Solution for Inhalation 3mg/3 mL Lot#: 324261 Expiration: 07/31/2025. After incubating the SDA canister at 20 – 25 C for one (1) day, you identified turbidity and thereby stopped the incubation process to proceed with subculturing for microbial identification. After failing to obtain viable growth on the subcultures, your quality unit concluded the turbidity observed did not contain viable microorganisms and ultimately invalidated the original sample without determining root cause for the turbidity. Per your written procedure MTM-SC-MB-6308 entitled, "Sterility Test Procedures" Revision: 39 Effective: 18-APR-2025, which is written based on USP <71>, samples are only invalidated for the four (4)

AMENDMENT 1

reasons:

a. "The data of the microbiological monitoring of the sterility test environment shows a fault.
b. A review of the testing procedure used during the test in question reveals a fault.
c. Microbial growth is found in the negative controls.
d. Upon determination of the identity of the micro-organisms isolated from the test, the growth of the species isolated may be ascribed unequivocally to faults with respect to the material and/or the technique used in conducting the sterility test."

Per your Director of Microbiology, the invalidated sample did not fall within any of these conditions.

OBSERVATION 4

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Sterile Drug Manufacturing & 503B Outsourcing Facility

Specifically,

1. Your firm's visual inspection methods used for inhalation products are inadequate. Currently, this inspection process for visible particulates, discoloration or turbidity, a critical defect, includes inspecting 50 blow fill seal (BFS) units per hour and AQL sampling at level 0.065%. Your process has not been validated to ensure your inspection method can adequately detect these defects in all products effectively across all inspectors. In 2025, you generated approximately five (5) defects generated for particles, cloudy, white specks, and dark particles.

2. You do not have sound scientific justification for not performing visual inspection for identifying

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025*
	FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lou Kennedy , CEO	
FIRM NAME Nephron Sc Inc	STREET ADDRESS 4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturing & 503B Outsourcing Facility

particulates, a critical defect in blow fill seal ophthalmic products manufactured in your facility.

3. Your 100% visual inspection program used for inspecting injectable products is deficient for the following reasons:

    a. Your 100% visual inspection program does not challenge robust, worst-case conditions for identifying defects of varying criticality for sterile liquid injectable drug products manufactured in your facility. Currently, your program qualifies your inspectors for (1) one hour whereas your shift is for 12 hours. Based on the validated batch sizes for products manufactured at your facility, inspectors are required to demonstrate competency in only a fraction of the units identified below. For example, for Sterile Water for Injection USP, inspectors are deemed qualified after evaluating a single tray containing 296 units with 34 defects at 100% competency, whereas the theoretical batch size yields 636,364 vials. This evaluation can occur up to three (3) times if failures are identified. Your visual inspection qualification does not demonstrate defect detection performance under actual production conditions.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Saundrea A Munroe, Investigator Rose L Jean-Mary, Investigator Kellia N Hicks, Investigator Simone E Pitts, National Expert X	8/22/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025*
	FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lou Kennedy , CEO

FIRM NAME	STREET ADDRESS
Nephron Sc Inc	4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
West Columbia, SC 29172-3025	Sterile Drug Manufacturing & 503B Outsourcing Facility

Product	Filling Line / Equipment	Batch Size	Theoretical Yield
Albuterol Sulfate Inhalation Solution, 0.5%	BFS Line 23	1,300 kg	242,991 Vials
1000 mL del Nido Cardioplegia Solution	Filling LFH	2,000 kg	1900 Bags
Lidocaine Hydrochloride Injection, USP 20 mg/4 mL (5 mg/mL)	BFS Line 24	908.5 kg	114,527 Vials
Ketamine Hydrochloride Injection, USP 50 mg/5 mL (10 mg/mL)	BFS Line 24	400 kg	72727 Vials
Neostigmine Methylsulfate Injection, USP 5 mg/5 mL (1 mg/1 mL)	BFS Line 24	200 kg	36364 Vials
Bupivacaine Hydrochloride Injection, 1 g/100 mL (1 mg/mL)	Kartel Filling Line	1,000 kg	2857 Bags
0.9% Sodium Chloride Injection, USP 300 mL	BFS Line 31	8,800 kg	17154 Bottles
Amino Acid Injection, 50 g/1000 mL (50 mg/mL)	Filling LFH	500 kg	188 Bags
Fentanyl Citrate in 0.9% Sodium Chloride Injection, USP 2500 mcg/250 mL (10 mcg/mL)	BFS Line 33	7,000 kg	7692 Bottles
Nephron SC, LLC			
Product	**Filling Line / Equipment**	**Batch Size**	**Theoretical Yield**
Ipratropium Bromide 0.5 mg & Albuterol Sulfate 3.0 mg Inhalation Solution	BFS Line 22 & 29	3,926 kg	1,238,48 vials
Ipratropium Bromide 0.5 mg & Albuterol Sulfate 2.0 mg Inhalation Solution	BFS Line 25, 26, 27, 28	8,800 kg	2,776,033 vials
Albuterol Sulfate Inhalation Solution, 0.08 %	BFS Line 31, 32, 26, 27	8,800 kg	2,776,033 vials
Albuterol sulfate Inhalation Solution, 0.08 %	BFS Line 29	5,000 kg	1,577,287 vials
Budesonide Inhalation Suspension 0.25 mg/2 mL and 0.5 mg/2 mL	BFS Line 22	3,500 kg	1,658,767 vials
Ipratropium Bromide Inhalation Solution 0.02%	BFS Line 23	5,032 kg	1,884,688 vials
Albuterol Sulfate Inhalation Solution, 0.5%	BFS Line 36	1,300 kg	2,095,774 vials
Albuterol Sulfate Inhalation Solution, 0.021% & 0.042%	BFS Line 27	3,925 kg	1,238,170 vials
Cysteine hydrochloride hydrochloride **ophthalmic solution**) 0.1%	BFS Line 36	700 kg	888,235 vials
Bacteriostatic Inhalation Solution, USP 0.9%	BFS Line 36	303 kg	488,710 vials
Sterile Water for Injection, USP 5mL	BFS Line 24	3,500 kg	636,364 vials
Polyethylene methacrylate chloride) Inhalation Solution Kit	BFS Line 24	400 kg	120,182 vials
Sodium Chloride Injection USP 50 mL, 100 mL, 250 mL, and 500 mL	Kartel Filling Line	500 kg	TBD
Ketorolac Tromethamine Injection, USP 60 mg/2 mL	BFS Line 23	500 kg	66,956 vials

* Inhalation product indicated on the product list are not included in the 100% visual inspection program SM 08/22/25

b. You did not establish a process to ensure created test kit defects are not memorized during qualification administration. Visual inspectors who require requalification or fail qualification are retested using the same kits, allowing for potential memorization of defective units. The same kits are reused for second and third attempts, as well as for annual visual inspection testing, increasing the risk that operators become familiar with known defects.

c. Your 100% visual inspection post-test qualification challenges inspector competency on product simulated kits created by visual inspection training supervisors rather than real product. You have not demonstrated these kits along with the created defects are equivalent to products manufactured in your facility and suitable for qualifying inspectors.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Saundrea A Munroe, Investigator Rose L Jean-Mary, Investigator Kellia N Hicks, Investigator Simone E Pitts, National Expert X	8/22/2025

d. You have not qualified the inspection procedure used to measure overfill volumes for sterile prefilled syringes for your 100% manual visual inspection processes for 503B operations. Currently, you use the graduations on retrofitted syringes to create sleeves which are used as measuring devices. These sleeves are intended to measure volume that exceeds the graduations applied the product's container closure system. These devices are uncontrolled and lack standardization.

e. The training of your 100% manual visual inspection trainers is inadequate in that they are deemed qualified on the test kits they create. Additionally, per your Quality Operations Sr. Manager, of the three (3) trainers, one (1) is not qualified to perform 100% visual inspection on product and the other two (2) have not performed any visual inspection on finished products manufactured at your facility in at least six (6) years. All trainers have the responsibility of confirming or invalidating defects identified by inspectors during manufacturing operations. For 2025, you generated approximately eight (8) 503B complaints related to missing label, plastic particles, plastic in port and leaking bags.

OBSERVATION 5

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Sterile Drug Manufacturing & 503B Outsourcing Facility

Specifically, your firm failed to follow procedures to ensure alarms impacting classified areas are promptly responded to, investigated, and corrected.

For example, during a walkthrough of the facility on 11 Aug 2025, we observed that the alarm for the Blow Fill Seal (BFS) "man" pass-through had been alarming for a significant amount of time. The

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025*
	FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lou Kennedy , CEO

FIRM NAME	STREET ADDRESS
Nephron Sc Inc	4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturing & 503B Outsourcing Facility

Material Transfer Operator (SL) present reported, "I don't do anything about alarms." The Corporate Chief Quality Officer confirmed the alarm had been active since that morning. She further reported that operators are trained to report and escalate alarms to management; however:

a. No operator reported or escalated the alarm.
b. No management oversight or monitoring of the alarm condition was evident.
c. No assessment was made regarding the potential impact of the alarm.
d. No investigation was initiated until we inquired.

Firm management later confirmed that the alarm indicated a differential pressure failure signifying loss of positive pressure from the ISO 7 area, which is the background area for BFS operations, and had a controlled not classified (CNC) area.

Your firm failed to ensure that alarms critical to maintaining aseptic conditions were promptly addressed, escalated, and investigated. These deficiencies in alarm management and oversight create an unacceptable risk of microbial ingress and contamination of sterile products. The lack of effective alarm response undermines sterility assurance and patient safety.

This is a repeated observation from the inspection performed 01/29/2024 – 02/09/2024.

OBSERVATION 6

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Sterile Drug Manufacturing & 503B Outsourcing Facility ~~NPC & 503B Operations~~ SM 08/22/2025

Specifically,

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Saundrea A Munroe, Investigator Rose L Jean-Mary, Investigator Kellia N Hicks, Investigator Simone E Pitts, National Expert X	8/22/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025*
	FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Lou Kennedy , CEO	
FIRM NAME Nephron Sc Inc	STREET ADDRESS 4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturing & 503B Outsourcing Facility

A. There is a failure of the Quality Unit (QU) to review and approve pre integrity filter testing that results in "abort" and "error." Pre-filter integrity outcomes resulting in abort or error are documented and maintained in the Pall Flowstar Integrity Tester and reviewed within the audit trails by Production management daily and quarterly. These records are not reviewed by the QU or evaluated prior to batch disposition.

503B Outsourcing Operations ~~503B Operations~~ SM 08/22/2025

[redacted]

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Saundrea A Munroe, Investigator Rose L Jean-Mary, Investigator Kellia N Hicks, Investigator Simone E Pitts, National Expert X	8/22/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	8/11/2025-8/22/2025*
	FEI NUMBER 3010892830

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Lou Kennedy , CEO

FIRM NAME	STREET ADDRESS
Nephron Sc Inc	4500 12th Street Ext
CITY, STATE, ZIP CODE, COUNTRY West Columbia, SC 29172-3025	TYPE ESTABLISHMENT INSPECTED Sterile Drug Manufacturing & 503B Outsourcing Facility

[redacted]

Your firm failed to ensure adequate control, oversight, and review of electronic records associated with the BFS system, including audit trails and error logs. These failures create significant risk that data critical to batch release decisions may be incomplete, inaccurate, or not available for review. The lack of Quality Unit oversight over electronic data compromises sterility assurance and patient safety.

***DATES OF INSPECTION**
8/11/2025(Mon), 8/12/2025(Tue), 8/13/2025(Wed), 8/14/2025(Thu), 8/15/2025(Fri), 8/18/2025(Mon), 8/19/2025(Tue), 8/20/2025(Wed), 8/21/2025(Thu), 8/22/2025(Fri)

X Kellia N Hicks
Investigator
Signed By: KELLIA N. HICKS -S
Date Signed: 08-22-2025 20:21:49

X Rose L Jean-Mary
Investigator
Signed By: 2002896516
Date Signed: 08-22-2025 20:22:24

X Simone E Pitts
National Expert
Signed By: Simone E. Pitts -S
Date Signed: 08-22-2025 20:23:05

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Saundrea A Munroe, Investigator Rose L Jean-Mary, Investigator Kellia N Hicks, Investigator Simone E Pitts, National Expert	X [redacted]	8/22/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

nephron

September 15, 2025

TO: **Electronic Mail:**
CDER-OC-OMQ-Domestic483Response@fda.hhs.gov;
CompoundingInspections@fda.hhs.gov

FROM: **Ashley Daugherty, PhD**
Corporate Chief of Quality and Compliance
Nephron SC, LLC
4500 12th Street Extension
West Columbia, SC 29172

Re: **15 Day Response to the Form FDA 483 Issued on August 22, 2025 to Nephron SC, LLC (FEIN 3010892830)**

This letter and its enclosures represent the 15 Day Response of Nephron SC, LLC ("Nephron") to the Form FDA 483 issued by the U.S. Food and Drug Administration ("FDA") at the conclusion of the inspection which occurred August 11-22, 2025. Nephron is a Section 510-registered manufacturer of FDA-approved prescription drug products, and a Section 503B-registered outsourcing facility located at 4500 12th Street Extension, West Columbia, SC (FEIN 3010892830).

As has been noted in previous communications to FDA concerning this inspection, Nephron had, at FDA's request, separately registered the sterile drug manufacturing (FEIN 3010892830) and outsourcing facility (FEIN 3011158388) operations. On August 11, 2025, a Form FDA 482 was presented to Nephron for each of the two (2) FEINs. It was not until the inspection close-out meeting on August 22, 2025 that Nephron was informed that the organizations would be "combined" and that 3010892830 would be the surviving FEIN. A single Form FDA 483 was issued which includes observations for both operations. On September 3, 2025, Nephron's counsel at Hyman, Phelps, & McNamara P.C. ("HPM") sent a letter to FDA detailing outstanding factual corrections to the Form FDA 483 and observations that we believe were inaccurately identified as repeats (*Attachment I*).

Nephron does not believe the Form FDA 483 as issued on August 22, 2025 accurately reflects the operational and GMP-compliance state of its facility, or the quality of the products manufactured therein. In addition to the concerns already communicated by HPM, Nephron believes that certain observations reflect a misunderstanding of FDA's own guidances, as well as industry standards from the United States Pharmacopeia ("USP"), and the Parenteral Drug Association ("PDA"). For example, Observation 4.1 inappropriately applies parenteral drug

product USP standards to an inhalation solution and Observation 4.2 rejects USP and PDA best practices for difficult to inspect parenteral products.

Additionally, Observations 1.A.b., 2.A, 2.B, and 4.3.d all concern manufacturing equipment (the Bausch 515 Automated Syringe Filler "BART") or container closure systems (prefilled syringes) not currently qualified for commercial use at Nephron. As previously committed, Nephron notified FDA on July 28, 2025 that it anticipated resuming commercial production on Bausch 515 Automated Syringe Filler ("BART") on or about August 27, 2025. Nephron has long been interested in FDA's input on its planned improvements to the BART. However, Nephron questions whether an FDA inspection was the most efficient or effective means to do so.

The investigators were clearly relaying feedback on the BART from FDA subject matter experts ("SMEs") who were off-site during the inspection. We recognize that is standard practice for investigators to consult with SMEs throughout an inspection. However, given that the BART is not commercially active and is currently under qualification, we question whether this was an effective use of resources during a lengthy ten (10) day inspection. Nephron would have appreciated the opportunity to discuss the BART with FDA SMEs directly which would have allowed the FDA investigators and Nephron personnel to focus on systems relevant to current production operations.

Product quality and patient safety are of upmost importance to Nephron. We remain committed to manufacturing both FDA-approved and sterile compounded drug products in accordance with GMP-requirements and respected industry standards. We will provide an update to this response, with the progress of all corrective preventive actions, no later than October 28, 2025. Please do not hesitate to contact Ashley Daugherty (adaugherty@nephronpharm.com), should you have any questions or require further clarification.

Sincerely,

Ashley Daugherty, PhD
Corporate Chief of Quality and Compliance
Nephron SC, LLC
4500 12th Street Extension
West Columbia, SC 29172-3025

Please note, this response contains trade secret and confidential commercial information subject to exceptions from public disclosure. We therefore respectfully request that the Agency treats this response as Freedom of Information Act exempt under, inter alia, 21 C.F.R. Part 20; and provide Nephron an opportunity to review any potential release of information contained in this letter or its enclosures/attachments therein.

Enclosures:

- Attachment I: Correspodence for Amended Form FDA 483 Issued to Nephron SC, LLC (FEIN 3010892830)
- 15 Day Response to the Form FDA 483 Issued on August 22, 2025 to Nephron SC, LLC (FEIN 3010892830)- *Submitted via box and portal provided due to file size*



Nephron, SC LLC
Nephron Sterile Compounding Center, LLC
FEI: 3010892830

15-Day Response
Dates of Inspection: August 11 – 22, 2025

Table of Contents

OBSERVATION 1 A: 6
OBSERVATION 1 B: 11
OBSERVATION 1 C: 17
OBSERVATION 1 D: 20
OBSERVATION 2 A: 23
OBSERVATION 2 B: 27
OBSERVATION 3.1: 31
OBSERVATION 3.2: 34
OBSERVATION 3.3: 35
OBSERVATION 4.1: 41
OBSERVATION 4.2: 44
OBSERVATION 4.3 a b c e: 48
OBSERVATION 4.3 d: 52
OBSERVATION 5: 54
OBSERVATION 6 A: 58
OBSERVATION 6 B: 60

ATTACHMENTS

1. PQ-AVS-2400-NOF0214 Documents
2. PQSR-AVS-2400-NOF0214 Study Video
3. Laminar Flow Hood (LFH) Smoke Study Storyboard
4. Laminar Flow Hood Risk-Based Impact Assessment
5. PQ-AVS-2501-282G Protocol 7-10-2025X
6. PQ-AVS-2501-282G Addendum 1 Executed
7. PQ-AVS-2501-282G Addendum Location #01, PQ-AVS-2501-282G Addendum Location #02, PQSR-AVS-2501-282G Addendum 1 - Summary
8. SOP.CM.4924 *Operation of the Bausch 515 Filling and Closing Machine e*
9. Non-Viable Particulate Comparison 8.18.25
10. PQ-AVS-2500-NOF0179
11. PQ-AVS-2500-NOF0181
12. Risk Based Impact Assessment LFH Airflow Visualization Study
13. Annual Contamination Control Strategy Review: 2024 Summary Report
14. QIP-23-008 *Compliance Enhancement Plan*
15. CAPA-0000049 Smoke Study Procedure Deficient
16. SOP-SC-MB-4509 – *Aseptic Techniques*
17. SOP.CM.4930 – *Manual IV Bag Filling Operations Procedure*
18. SOP-SC-MB-4511 – *Environmental and Personnel Monitoring*
19. SOP.SR.4902 – *Cleaning of Horizontal Laminar Flow Hoods*
20. SOP-SC-MB-4510 – *Sanitization and Transfer of Parts to a Classified Environment*
21. Q1 2025 EM/PM Trend Report
22. FRM-SC-MB-4509-A, *Aseptic Technique Observation Checklist*
23. FRM.TD.1603.H, *On The Job (OJT) Certification – 503B Filling – General Aseptic Operations*
24. SOP-SC-MB-4551, *Gowning Procedure*
25. FRM.CM.1604.D, *Aseptic Process Simulation-IV Bag Intervention Form*
26. Abbreviated Risk Management Report Obs 1 and 2 FDA Inspection 8-11 – 22- 2025
27. CAPA-0000054 Operator Training Enhandment to add Airflow Visualization Demonstration
28. CAPA-0000038 Procedure Updates related to Intervention Documentation and Trending
29. MPL-SC-MB-0111, *Aseptic Process Simulation - Media Fill - Master Plan*
30. Steris Surface Disinfectant Efficacy Study
31. SOP-SC-MB-6204, *Microbial Excursions and Deviations*
32. Environmental Monitoring Data From 8-2023 to 8-2025
33. Personnel Monitoring Data for Glove Sites From 8-2023 to 8-2025
34. CAPA 0000042 Completion of Sanitize Efficacy Study of Nitrile Gloves
35. SOP-SC-TD-1610, *Training Program*
36. WRK-SC-SR-4530-K, *Cleaning/Sanitizing Automated Filling Suites*
37. SOP-SC-MB-4542, *Environmental Monitoring Performance Qualification Process*
38. WRK-SC-MB-4542-A, *Instructions for drafting Environmental Monitoring Performance Qualification*
39. PQ-464C, *Addendum to Environmental Monitoring Performance Qualification for Suite 282 (BART)*
40. SOP-SC-QA-1154, *Risk Management*
41. 282 Suite CRR Viable Trend
42. 1031030 Damaged PM Sample for Cleanroom QA Not Incubated for Lot #: KH4001A
43. PR 1031440 CAPA to Track Execution of MP-608 and Completion of Summary Report
44. PR 1031442 CAPA to Track Creation of Placement of Personnel Monitoring Work Aids
45. WRK-SC-MB-4511-I, *Personnel Monitoring Work Instruction*

46. 3.1 CAPA Summary Table
47. Action 254
48. SOP-SC-MB-6220, *Environmental Monitoring Incubation and Enumeration*
49. WRK-SC-MB-6220-C, *Sample Incubation Decision Tree*
50. CAPA 0000052 Incorporation of Media Qualification Plan
51. CAPA 0000053 Definition of Sample Transport Process for EM and PM Samples
52. SOP-SC-MB-6265, *Environmental Action Committee*
53. SOP-SC-MB-4516, *Environmental Monitoring Quarterly Trend Report*
54. CR# 12505 90 mm Tryptic Soy Agar (TSA) plates Used for personnel monitoring
55. CAPA 0000054 Incorporation of Media Qualification Plan
56. Microbiology PM Program
57. MTM-SC-MB-6308, *Sterility Test Procedures*
58. NPC-ER-MQC-23-025
59. CAPA 0000047 Inspection Finding for Inspection of Inhalation Products
60. SOP-SC-QA-5202, *Finished Product Attribute Inspection*
61. SOP-SC-QA-1104, *Responsibilities of the Quality Unit*
62. FDA interpretation memo clarifying the regulatory basis under USP <5> for inhalation solutions
63. CR-05451, *Visual Inspection of Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1%*
64. PDSR-22-219
65. Justification for Removal of 100% Visual Inspection of Oxymetazoline Hydrochloride Ophthalmic Solution 0.1%
66. Memorandum CTM-SC-AS-6656 (CR-06268) "Particulate Matter Testing of Oxymetazoline HCl 0.1% Ophthalmic Solution
67. SR-SC-CTM-6656-001
68. CR-06291 IPS-SC-AS-4219, *Oxymetazoline HCl Ophthalmic Solution, 0.1% WIPS In Process Product Specification*
69. JOS-CR-06291-01, *Justification of Specifications for IPS-SC-AS-4219, Oxymetazoline HCl Ophthalmic Solution, 0.1 WIPS In Process Product Specification*
70. FRM-SC-QA-1901-A, *Customer for Contract Manufacturing Review and Approval Form* for PDSR-22-226
71. One (1) photo of a five (5) vial card of Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1% on the black background of a Light Booth
72. One (1) photo of a five (5) vial card of Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1% on the white background of a Light Booth
73. Action 434 – Complaint Log Oxymetazoline Last 3 Years
74. SOP-SC-QA-4366, *Quality Attribute Testing - Visual Inspection*
75. SOP-SC-QA-1606, *Visual Inspection Training and Certification*
76. SOP-SC-QA-1201, *Fabrication and Maintenance of Visual Inspection Test Kits*
77. Floor Plan Manufacturing Building 1st Floor
78. SOP-SC-QA-1216 *TopView Alert Notification System*
79. SOP-SC-QA-1217 *Alarm Annotation System*
80. SOP-SC-QA-2530, *Cleanroom Operation and Inspection*
81. CAPA #: 1033175, *Modification to Operator Response Workflow for Stack Lights and Magnehelic Gauges*
82. WRK-SC-BR-1250-A, *Work Instructions for the Review of Batch Record*
83. SOP-SC-FM-4111 *Management of Filters*
84. SOP-SC-PR-4399, *Audit Trail Review BFS*

85. SOP-SC-BR-1250, *Finished Product Batch Review and Release*
86. SOP-SC-IT-9301, *Electronic Data Backup*
87. CAPA 0000050 Audit Trail
88. Rommelag Clarification- BFS Audit Trail Artifacts
89. PD-22-226
90. CAPA 0000040, Procedural and Training Updates
91. MPL-SC-MB-0110, *Microbiological Test Method Validation Master Plan*
92. PQ-607, Performance Qualification of the Veeam Backup Solution

OBSERVATION 1 A:

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and written.

Specifically,

A. Your firm failed to perform adequate airflow-visualization (smoke) studies under dynamic conditions representative of actual aseptic operations. Specifically, for example, but not limited to, the following:

a. Laminar Flow Hood (LFH) Equipment: Smoke studies for the LFH was not conducted under dynamic conditions representative of actual operations. The studies did not demonstrate unidirectional airflow protection of all critical zones during interventions, including set-up and material manipulations.

b. BART Syringe Filler (Room 282G, Equipment ID/NID # NOF-01117): Airflow visualization (smoke studies) for the BART syringe filler were not performed under dynamic conditions representative of actual aseptic operations, including interventions and operator activities. The current approved study did not demonstrate that unidirectional airflow is maintained over all critical zones to protect exposed sterile product from contamination.

c. Cleanroom Design / LFH Placement: The main cleanroom door is directly in line with the LFH. During filling operations, this door was observed to be opened multiple times, creating the potential for airflow disruption and loss of ISO 5 protection in the LFH critical zone. This scenario was not simulated in your smoke studies and has not been evaluated under actual operational conditions.

Your firm failed to demonstrate through scientifically sound smoke studies that unidirectional airflow and first air are consistently maintained in ISO 5 classified areas during actual aseptic processing an including activity in the background environment which can disrupt airflow. Without adequate airflow visualization, sterile products may be produced in an environment that does not provide sufficient protection against microbiological contamination.

RESPONSE 1.A a.

The Nephron approach to airflow visualization studies within each ISO 5 Laminar Flow Hood (LFH) is in alignment with Annex 1 and FDA's Guidance for Industry, *Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice* (October 2004). During the FDA Audit on August 14 and 15, auditors were provided objective evidence, including documentation package and airflow visualization studies (video footage), for LFH NOF 0214 in room M119. The studies demonstrated that critical zones remained protected, and ingress was prevented during interventions and background activities.

Dynamic conditions assessed in the study included LFH pre-use cleaning, setup and purging of the product pathway, material introduction and IV bag outer packaging removal, filling and operator interventions as simulated in media fills, and the number of personnel present for both critical and background activities. The studies were reviewed and approved by Production Management, Microbiology, Validation, and Quality Assurance. Results confirmed that unidirectional airflow was consistently maintained across the ISO 5 filling area, that first-air protection of the critical zones, including luer-lock and transfer port was continuous, and that no turbulence, reverse airflow, or ingress from the surrounding environment was observed.

During the prior inspection (ending September 25, 2024), airflow visualization studies were also demonstrated using the same study design. The equivalent airflow visualization study, provided on LFH NOF 0181 in room M123 was reviewed and deemed acceptable by FDA without comment.

Immediate Actions:
During the inspection on August 14 & 15, 2025, Nephron provided investigators with the executed smoke study protocol (PQ-AVS-2400-NOF0214 Execution Scan) and summary report (PQSR-AVS-2400-NOF0214), hood qualifications and certifications (Attachment 1), and a copy of the study video (PQSR-AVS-2400-NOF0214.mp4, Attachment 2). At the inspectors' request, on August 20, 2025, additional clarifying materials were presented, including a storyboard (Attachment 3) and a risk-based impact assessment (Attachment 4). These emphasized that all ISO 5 interventions were fully captured under dynamic, worst-case conditions consistent with FDA guidance, *Sterile Drug Products Produced by Aseptic Processing* (October 2004). Although not all ISO 7 activities were filmed in full, ISO 7 tasks were risk-assessed and shown not to impact ISO 5 critical zones, and their controls are demonstrated through boundary smoke studies, hood qualifications, pressure cascades, air change rates, and environmental monitoring trends.

b. BART Syringe Filler (Room 282G, Equipment ID/NID # NOF-01117): Airflow visualization (smoke studies) for the BART syringe filler were not performed under dynamic conditions representative of actual aseptic operations, including interventions and operator activities. The current approved study did not demonstrate that unidirectional airflow is maintained over all critical zones to protect exposed sterile product from contamination.

RESPONSE 1 A b:
Airflow visualization studies were recently performed on the ISO 5 barrier of the Bausch 515 Automated Syringe Filler (BART) (Room 282G, Equipment ID/NID # NOF-01117) in accordance with Annex 1 and FDA Guidance, following design enhancements to the system. These studies were performed as part of ongoing qualification activities as the BART syringe filler is not currently used in commercial production. At the auditors' request, study documentation and video footage were provided onsite on August 14 and 15, 2025, demonstrating unidirectional airflow across the machine surface, protection of critical zones, and prevention of ingress during interventions and background activities.

Prior to execution, a design failure modes and effects analysis (dFMEA) was conducted to evaluate the potential impact of design changes on airflow and to identify the most critical interventions requiring evaluation. This risk-based approach ensured that airflow visualization focused on those operations with the greatest potential impact on product sterility.

Dynamic conditions assessed included equipment setup as well as glove-port interventions such as settle plate placement, product purging, syringe loading, cap charging, and jam clearance.

The studies, reviewed and approved by Production Management, Microbiology, Validation, and Quality Assurance, confirmed that unidirectional airflow was consistently maintained across all critical zones, that no ingress of air into ISO 5 areas occurred during interventions, and that no turbulence or reverse airflow was observed that could compromise sterility.

Immediate Actions:
Nephron provided FDA with the *BART Process Rationalization Presentation* (Attachment 3), the executed smoke study protocol (PQ-AVS-2501-282G Protocol 7-10-2025, Attachment 5), and summary report (PQSR-AVS-2501-282G, Attachment 1), the corresponding study video (PQ-AVS-2501-282G.mp4, Attachment 3), and room 282G certification documentation under Action 117 and Action 121.

During review of the airflow visualization study, inspectors relayed concerns that (i) smoke was not clear during settle plate placement (Time Point 47:31- 49:43), (ii) the study did not capture the displacement of caps into the capping bowl (Time Point 33:53 - 34:32), and (iii) glove movement was observed directly above an isokinetic probe (Time Point 46:23 - 4). Inspector feedback was constructively used to strengthen the documentation record. Nephron again affirmed to investigators that the BART syringe filler is not in commercial production and that no syringe products within expiry are on the market.

On August 22, 2025, preliminary reshoots of settle plate placement and cap displacement into the capping bowl were performed, demonstrating that unidirectional airflow was maintained at all times. Because the isokinetic probe is specifically designed to detect particulate generated by interventions within the enclosure, no additional action was warranted for this point.

An addendum protocol (PQ-AVS-2501-282G Addendum 1 Executed, Attachment 6) to the BART smoke study protocol was executed to formally capture the reshoots of settle plate placement (Location 01) and cap displacement into the capping bowl (Location 02). The results further demonstrated that unidirectional airflow was maintained at all times (PQ-AVS-2501-282G Addendum Location #01, PQ-AVS-2501-282G Addendum Location #02, PQSR-AVS-2501-282G Addendum 1 – Summary, see Attachment 7). Additionally, the *BART Process Rationalization Presentation* (Attachment 3) was updated to ensure it is clear the current process requires all operator interventions within the ISO 5 barrier, when product is present, to be performed exclusively via glove ports in accordance with SOP.CM.4924 *Operation of the Bausch 515 Filling and Closing Machine* (Attachment 8).

As the system is not in commercial production, these activities have been appropriately documented within the ongoing change record supporting commercial development.

In summary, Nephron has conducted airflow visualization studies under dynamic, worst-case conditions for the BART syringe filler in accordance with Annex 1 and FDA guidance. Supported by a risk-based design assessment and subsequent clarifications, these studies confirm that unidirectional airflow and first-air protection are consistently maintained across all critical zones. Activities arising from inspector feedback have been integrated into the ongoing change record to ensure the system is fully validated prior to commercial production.

c. Cleanroom Design / LFH Placement: The main cleanroom door is directly in line with the LFH. During filling operations, this door was observed to be opened multiple times, creating the potential for airflow disruption and loss of ISO 5 protection in the LFH critical zone. This scenario was not simulated in your smoke studies and has not been evaluated under actual operational conditions.

RESPONSE 1 A c:
The main cleanroom door adjacent to the LFH was noted by investigators as a potential source of airflow disruption during filling operations, due to door openings observed while aseptic activities were ongoing. The main cleanroom door and LFH have been in their present locations for over 5years, as has been

observed without comment or concern in 4 prior FDA inspections. While prior airflow visualization studies focused on ISO 5 interventions, this specific background scenario had not been directly included in earlier simulations. Industry standards, regulatory guidance, and Nephron's established practice appropriately emphasize airflow visualization of ISO 5 critical zones where sterile product is exposed, as these areas present the highest risk for contamination and are the focus of Annex 1 and FDA's aseptic processing guidance.

Total particulate environmental monitoring data collected in tandem for dynamic room monitoring and continuous hood monitoring was provided to inspectors (Attachment 9) for the filling process observed on August 18, 2025 further demonstrated that both ISO 7 background and ISO 5 LFH conditions remained in a state of control, regardless of door openings or other background activities.

Immediate Actions:
At the time of inspection, FDA feedback was noted in addition to the scientific, industry-aligned evidence already provided, which demonstrated that ISO 5 conditions were in control. As an opportunity for improvement and to further strengthen the airflow visualization record, Nephron executed additional airflow visualization protocols under PQ-AVS-2500-NOF0179 (PQ-AVS-2500-NOF0179 Executed, PQ-AVS-2500-NOF0179 Location #01, PQ-AVS-2500-NOF0179 Location #02, PQ-AVS-2500-NOF0179 Location #03, PQSR-AVS-2500-NOF0179 – Summary, see Attachments 10) and PQ-AVS-2500-NOF0181 (PQ-AVS-2500-NOF0181 Executed, PQ-AVS-2500-NOF0181 Location #01, PQ-AVS-2500-NOF0181 Location #02, PQ-AVS-2500-NOF0181 Location #03, PQSR-AVS-2500-NOF0181 – Summary, see Attachments 11). These studies incorporated representative ISO 7 background activities, including door movement and all representative background activities in filling suites M122 and M123, while ISO 5 LFH operations were underway. The studies, reviewed and approved by Production Management, Microbiology, Validation, and Quality Assurance, demonstrated that unidirectional airflow was consistently maintained across ISO 5 critical zones, that critical connection points (e.g., luer lock and fluid transfer port) remained continuously protected by unobstructed first air, and that no turbulence, reverse airflow, or ingress from ISO 7 areas was observed.

Risk Based-Impact Assessment:
A risk assessment was conducted for each of the observations surrounding cleanroom operations and environmental control, which included all findings within Observation #1A (Attachment 12). All risks associated with airflow due to process design were found to be low-risk due to strength of controls currently established. Data review from existing detectability controls confirmed the system is currently operating in control with no impact to product on the market.

The *Annual Contamination Control Strategy Review: 2024 Summary Report* (Attachment 13) was provided during the inspection on 8/13/2025 in Action 125. On page 38 of 42, a summary of contamination control risk assessments is included. In summary, this report confirmed:

- Data review confirmed the system is operating in control
- Risk assessment updates are planned and in-progress for both Nephron SC LLC and Nephron Sterile Compounding Center LLC
- The contamination control risk assessments for Nephron SC LLC and Nephron Sterile Compounding Center LLC will be combined into one risk assessment for Nephron
- Significant pre-work was acknowledged for risk assessments in-progress for legacy processes, including development of extensive process maps for comprehensive hazard identification

- Priorities for risk assessment updates are driven by most commonly used production processes and introduction of new processes which could impact risk profile

In anticipation of resuming production following BART re-design, design and process risk assessments were prioritized for BART and related Quality Risk Management Plans were provided to inspectors 8/13/2025. Legacy risk assessments were additionally provided in support of the existing laminar flow hood process upon request. Nephron recognizes risk assessments for the laminar flow hood process require update and revisions are underway. Nephron self-identified enhancements to the Quality Risk Management Program were needed following warning letters received in October of 2022. The program enhancements are outlined below:

- **April 2024**: Dedicated Quality Management role developed to build upon the existing Quality Risk Management Program as part of Quality Improvement Plan QIP-23-008, *Compliance Enhancement Plan* (Attachment 14).
- **September to December 2024**: Nephron engaged ValSource, a leading third-party firm in Pharmaceutical Quality Risk Management, to perform a Quality Risk Management Maturity Assessment.
- **February 2025**: Nephron engaged ValSource to hold an intensive on-site training for Quality Risk Facilitators.
- **July 2025**: Quality Risk Management Program restructure initiated through Quality Improvement Plan QIP-25-002 *Quality Risk Management Program Enhancements*.

Corrective and Preventive Actions (CAPA-0000049 due December 11, 2025):

The root cause of the investigation identified that airflow visualization (smoke) study protocols did not fully account for dynamic, worst-case aseptic operations (e.g., material manipulations, background activities, and potential airflow disruptions). This resulted from historical emphasis on ISO 5 zones only, without consistent integration of ISO 7 background simulations and intervention-specific documentation. To address these findings, a CAPA (CAPA-0000049, Attachment 15) has been initiated, targeted for implementation by December 11, 2025.

1. **Corrective Procedural Revisions and Documentation Enhancements**
   SOP-SC-CA-2531, *Airflow Visualization Study Procedure* to require (i) Dynamic simulations including representative interventions, background activities, and door movements, (ii) justification of smoke clip selection and camera angles, (iii) inclusion of ISO 7 activities when they may affect ISO 5 zones.

2. **Preventive Actions**
   - Update and harmonize the Contamination Control Risk Assessment to include LFH aseptic processes.
   - Strengthen connection between airflow visualization and periodic qualification lifecycle review
   - Strengthen training for Production, Microbiology, Validation, and QA personnel on airflow visualization expectations and aseptic interventions.

3. **Effectiveness Check(s)**
   - Audit of at least one smoke study execution under the revised procedure to verify adherence.
   - Confirm risk assessment update includes LFH aseptic processes by documented QA review.

- Trend EM and particulate data for 6 months post-implementation to verify continued control of ISO 5 and ISO 7 zones and no increase trends have been identified.

Collectively, in response to Observation 1.A and its subparts, Nephron has provided objective evidence, conducted confirmatory studies, and implemented enhancements to ensure both immediate remediation and future prevention through strengthened controls. Comprehensive airflow visualization studies under dynamic, worst-case conditions confirm that unidirectional airflow is consistently maintained in both the ISO 5 LFHs and the ISO 5 BART syringe filler barrier during all interventions, regardless of door openings or background activities. These actions reinforce Nephron's commitment to sustainable compliance, robust contamination control, and continuous improvement in full alignment with FDA expectations. Nephron remains fully committed to sustaining these improvements and maintaining a state of control.

OBSERVATION 1 B:

Your firm failed to demonstrate through scientifically sound smoke studies that unidirectional airflow and first air are consistently maintained in ISO 5 classified areas during actual aseptic processing and including activity in the background environment which can disrupt airflow. Without adequate airflow visualization, sterile products may be produced in an environment that does not provide sufficient protection against microbiological contamination.

Specifically,

Your firm failed to adequately control aseptic operations, enforce proper personnel practices and implement effective contamination controls. These deficiencies in aseptic practices create an unacceptable risk of microbial contamination to sterile drug products administered directly to patients' cardiovascular systems. For example, but not limited to, during the aseptic filling of Batch #NC-5128A of 1000 ml Del Nido Cardioplegia Solution in Laminar Flow Hood (LFH)-0179. Room M122, and Batch #NC-5128B in LFH-0181, Room M123, we observed the following poor aseptic practices:

Subparts 1-9:

1. ***Your firm failed to sanitize IV bags prior to their introduction into ISO 5 laminar flow hoods; operators transferred overwrapped IV bags from the ISO 7 area and placed them directly on critical surfaces without wiping with new sterile IPA wipes.***
2. ***Your firm failed to ensure operators performed slow and deliberate movements in the ISO 5 critical area; operators were observed moving rapidly in a manner that disrupted unidirectional airflow.***
3. ***Your firm failed to require operators to sanitize their hands prior to transferring materials into the ISO 5 area.***
4. ***Your firm failed to control the cleanroom environment; trash removal was conducted while filling operations were in progress without halting production.***
5. ***Your firm failed to prevent unnecessary particulate generation; operators moved shelving containing tubs of filled and bulk IV bags during active filling.***
6. ***Your firm failed to maintain segregation and control of critical areas; the main doors to manufacturing rooms were opened during aseptic operations, and in Room M122 the door was directly in line with the critical surface of the LFH.***
7. ***Your firm failed to enforce proper gowning practices; operators were observed removing and replacing sleeves and gloves in the background area during filling operations.***
8. ***Your firm failed to ensure disinfectants and sanitizing materials were used appropriately; IPA wipes intended for single use were reused multiple times after being left exposed on shelving.***

9. ***Your firm failed to ensure the integrity of personnel monitoring data; a microbiologist was observed spraying his hands with disinfectant immediately prior to performing his own personnel monitoring, thereby biasing results.***

Response 1B:
We acknowledge the FDA observation and recognize the critical importance of proper aseptic techniques in maintaining the integrity of sterile drug products and ensuring patient safety. Aseptic practices are a fundamental component of our quality system, and we are fully committed to upholding the highest standards.

Immediate Actions:
During the inspection (08/11/2025 – 08/22/2025), FDA inspectors engaged with Nephron personnel regarding aseptic processes for 503B sterile room IV bag production. In real time, while reviewing production operations, Nephron provided hard copies of governing SOPs including:

- SOP-SC-MB-4509 – *Aseptic Techniques* (Attachment 16)
- SOP.CM.4930 – *Manual IV Bag Filling Operations Procedure* (Attachment 17)
- SOP-SC-MB-4511 – *Environmental and Personnel Monitoring* (Attachment 18)
- SOP.SR.4902 – *Cleaning of Horizontal Laminar Flow Hoods* (Attachment 19)
- SOP-SC-MB-4510 – *Sanitization and Transfer of Parts to a Classified Environment* (Attachment 20)

An internal investigation (DEV-0000116) was opened to evaluate aseptic operations, review video and EM data, and determine the accuracy and impact of each subpart of the observation. As a precaution, Lot# NC5128A and Lot# NC5128B were placed on quality hold until this investigation (DEV-0000116) was completed.

1.B; Subpart 1: Your firm failed to sanitize IV bags prior to their introduction into ISO 5 laminar flow hoods; operators transferred overwrapped IV bags from the ISO 7 area and placed them directly on critical surfaces without wiping with new sterile IPA wipes.

RESPONSE 1.B, Subpart 1:
Investigation confirmed IV bags *were* sanitized prior to introduction into the LFH, per SOP.CM.4930, *Manual IV Bag Filling Operations Procedure*. Video review verified compliance with procedure. SOP-SC-PR-4510, *Sanitization and Transfer of Parts to a Classified Environment* contains specific instructions for sanitizing materials before placement in PEC; all components must be sanitized with sterile 70% IPA before entering ISO 5 areas.

Action:
Nephron self-identified an improvement opportunity prior to the inspection, with revisions actively in-progress. Change Control CC-0000066 was initiated to revise the material transfer process and enhance the LFH process flow.

1.B; Subpart 2:Your firm failed to ensure operators performed slow and deliberate movements in the ISO 5 critical area; operators were observed moving rapidly in a manner that disrupted unidirectional airflow.

RESPONSE 1B; Subpart 2:
Smoke study qualifications and EM results support operator movements do not compromise ISO 5 conditions, as evidenced during quarterly EM trending of ISO 5 laminar flow hoods (Attachment 21 – *Q1 2025 EM/PM Trend Report*, see pages 19-20). Nephron acknowledges an opportunity to reinforce training on slow, deliberate motion in ISO 5, consistent with SOP-SC-MB-4509, *Aseptic Techniques*.

Ongoing compliance with procedure is verified during routine aseptic observations, which are documented on FRM-SC-MB-4509-A, *Aseptic Technique Observation Checklist* (Attachment 22). The checklist contains specific items related to cleanroom behaviors during aseptic filling operations, including verification that personnel perform slow/deliberate movements within the hood.

Action:
Revision to FRM.TD.1603.H, *On The Job (OJT) Certification – 503B Filling – General Aseptic Operations*, (Attachment 23) to include smoke study demonstrations as part of aseptic training. The revision will clearly define operational movement standards in the cleanroom environment and emphasize slow and deliberate movements by utilizing smoke studies to visualize how movements affect airflow.

***1.B; Subpart 3:* Your firm failed to require operators to sanitize their hands prior to transferring materials into the ISO 5 area.**

RESPONSE 1B; Subpart 3:
Review confirmed proper sanitization occurred according to SOP-SC-MB-4509, *Aseptic Techniques* (Attachment 16), and SOP-SC-MB-4551, *Gowning Procedure* (Attachment 24) prior to material transfer into the LFH. Observation was found to be inaccurate.

Ongoing effectiveness verified through environmental and personnel monitoring trending (*Q1 2025 EM/PM Trend Report* – Attachment 21).

***1.B; Subpart 4:* Your firm failed to control the cleanroom environment; trash removal was conducted while filling operations were in progress without halting production.**

RESPONSE 1B; Subpart 4:
Trash was removed from ISO 7 background briefly in sealed bags while filling continued. The EM results, which are retained with the associated batch records for Lot# NC5128A and Lot# NC5128B, demonstrate the ISO 5 area remained in a state of control, as all results were below alert and action limits.

Immediate Action:
Airflow visualization studies, PQ-AVS-2500-NOF0179 and PQ-AVS-2500-NOF0181, were performed in M122 and M123 during operational conditions to demonstrate this activity (Attachments 10, PQ-AVS-2500-NOF0179 Executed, PQ-AVS-2500-NOF0179 Location #01, PQ-AVS-2500-NOF0179 Location #02, PQ-AVS-2500-NOF0179 Location #03, PQSR-AVS-2500-NOF0179 – Summary, PQ-AVS-2500-NOF0181 Executed, PQ-AVS-2500-NOF0181 Location #01, PQ-AVS-2500-NOF0181 Location #02, PQ-AVS-2500-NOF0181 Location #03, PQSR-AVS-2500-NOF0181 – Summary). The

results from both studies demonstrate the activities in the ISO 7 room do not disrupt the airflow patterns within the ISO 5 LFH.

Action:
SOP.CM.4930, *Manual IV Bag Filling Operations Procedure* to be revised to restrict trash removal to defined pauses or post fill only (Attachment 17).

1.B; Subpart 5: Your firm failed to prevent unnecessary particulate generation; operators moved shelving containing tubs of filled and bulk IV bags during active filling.

RESPONSE 1B; Subpart 5:
Investigation confirmed totes on shelving were moved as required by normal operations per SOP.CM.4930, *Manual IV Bag Filling Operations Procedure*. No environmental excursions occurred in the ISO 5 environment, and continuous particle monitoring remained within specifications; therefore, tote manipulation during filling operations was determined to have no impact.

Immediate Action:
Airflow visualization studies, PQ-AVS-2500-NOF0179 and PQ-AVS-2500-NOF0181, were performed in M122 and M123 during operational conditions to demonstrate this activity (PQ-AVS-2500-NOF0179 Executed, PQ-AVS-2500-NOF0179 Location #01, PQ-AVS-2500-NOF0179 Location #02, PQ-AVS-2500-NOF0179 Location #03, PQSR-AVS-2500-NOF0179 – Summary, PQ-AVS-2500-NOF0181 Executed, PQ-AVS-2500-NOF0181 Location #01, PQ-AVS-2500-NOF0181 Location #02, PQ-AVS-2500-NOF0181 Location #03, PQSR-AVS-2500-NOF0181 – Summary). The results from both studies demonstrate the activities in the ISO 7 room do not disrupt the airflow patterns within the ISO 5 LFH.

1.B; Subpart 6: Your firm failed to maintain segregation and control of critical areas; the main doors to manufacturing rooms were opened during aseptic operations, and in Room M122 the door was directly in line with the critical surface of the LFH.

RESPONSE 1B; Subpart 6:
Doors were briefly open; differential pressure remained within specification, with no viable or non-viable excursions.

Immediate Action:
Airflow visualization studies, PQ-AVS-2500-NOF0179 and PQ-AVS-2500-NOF0181, were performed in M122 and M123 during operational conditions to demonstrate this activity (PQ-AVS-2500-NOF0179 Executed, PQ-AVS-2500-NOF0179 Location #01, PQ-AVS-2500-NOF0179 Location #02, PQ-AVS-2500-NOF0179 Location #03, PQSR-AVS-2500-NOF0179 – Summary, PQ-AVS-2500-NOF0181 Executed, PQ-AVS-2500-NOF0181 Location #01, PQ-AVS-2500-NOF0181 Location #02, PQ-AVS-2500-NOF0181 Location #03, PQSR-AVS-2500-NOF0181 – Summary). The results from both studies demonstrate the activities in the ISO 7 room do not disrupt the airflow patterns within the ISO 5 LFH.

Action:

SOP.CM.4930, *Manual IV Bag Filling Operations Procedure,* to be revised to reinforce procedural emphasis on minimizing door openings (Attachment 17).

***1.B; Subpart 7:* Your firm failed to enforce proper gowning practices; operators were observed removing and replacing sleeves and gloves in the background area during filling operations.**

RESPONSE 1B; Subpart 7:
Confirmed sleeve and glove changes occurred by the EM technician as part of personnel monitoring bracketing. It was not a production operator removing/replacing sleeves during filling. Video review corroborates the EM technician completed room monitoring and then performed the glove/sleeve change as required by SOP-SC-MB-4511, *Environmental and Personnel Monitoring* (Attachment 18).

***1.B; Subpart 8:* Your firm failed to ensure disinfectants and sanitizing materials were used appropriately; IPA wipes intended for single use were reused multiple times after being left exposed on shelving.**

RESPONSE 1B; Subpart 8:
No reuse of wipes was identified. One instance of an unused wipe left on shelving after being removed from the original container was investigated; the wipe was discarded, not reused.

***1.B; Subpart 9:* Your firm failed to ensure the integrity of personnel monitoring data; a microbiologist was observed spraying his hands with disinfectant immediately prior to performing his own personnel monitoring, thereby biasing results.**

RESPONSE 1B; Subpart 9:
The investigation confirmed the Environmental Monitoring technician was following established procedural controls as outlined in SOP-SC-MB-4509, *Aseptic Techniques* (Attachment 16) and SOP-SC-MB-4511, *Environmental and Personnel Monitoring* (Attachment 18). While the observation described a microbiologist spraying their gloves with disinfectant immediately prior to performing their own personnel monitoring, our investigation revealed the EM technician first sanitized their gloves prior to plating an operator, and then approximately one minute later, performed his own monitoring. This sequence is in accordance with procedure, which specifically prohibits sanitization immediately before self-plating while requiring EM technicians sanitize gloves in-between operator plating sessions. Although time difference between plating and EM technician glove sanitization is brief, this practice aligns with plating process flow and reduces the risk of the EM technician potentially contaminating the production operator's results, as the EM technician is responsible for manipulating plates for all technicians associated with IV bag filling production.

Risk Based-Impact Assessment:
A risk assessment was conducted for each of the observations surrounding cleanroom operations and environmental control, which included all findings within Observation #1A and #1B (Attachment 26 – *Risk Report*). There were no high or severe risks identified. The risk profile primarily contained low risks, however there were two hazards which Nephron determined mitigation action will be pursued (medium-risk). There was one medium risk which required acceptance, though enhancements will be pursued to strengthen existing controls. These hazards are listed in Table 1.B.9-1, below, with applicable actions. Data review from existing detectability controls confirmed the system is currently operating in control with no impact to product on the market. Specifically, airflow visualization studies, PQ-AVS-2500-NOF0179 and

PQ-AVS-2500-NOF0181, were performed in M122 and M123 during operational conditions to demonstrate this activity (Attachments PQ-AVS-2500-NOF0179 Executed, PQ-AVS-2500-NOF0179 Location #01, PQ-AVS-2500-NOF0179 Location #02, PQ-AVS-2500-NOF0179 Location #03, PQSR-AVS-2500-NOF0179 – Summary, PQ-AVS-2500-NOF0181 Executed, PQ-AVS-2500-NOF0181 Location #01, PQ-AVS-2500-NOF0181 Location #02, PQ-AVS-2500-NOF0181 Location #03, PQSR-AVS-2500-NOF0181 – Summary). The results from both studies demonstrate activities in the ISO 7 room do not disrupt the airflow patterns within the ISO 5 LFH.

Table 1.B.9-1: Overview of Hazards Identified in Risk Based-Impact Assessment

Hazard ID #	Process	Risk Statement	Risk Level	Mitigation Action	Assigned to
1.B.3	Laminar flow hood	If operators do not sanitize their gloves prior to transferring materials into the laminar flow hood during active filling, contamination on gloves could be transferred to materials/surfaces in the laminar flow hood upon transfer, later potentially entering finished product during filling manipulations through mechanical transfer.	R2 - Medium	**Eliminate hazard:** Procedure will be updated to provide instructions for new method of material transfer into laminar flow hood within CC-0000066. Transfer personnel will no longer remove sterile IV bag from outer packaging and packaging will not be placed on surface of laminar flow hood.	Cleanroom Quality Assurance
1.B.8	Laminar flow hood	If sterile wipes are reused to sanitize components, there is potential to inadequately reduce contamination present the outer packaging of components prior to entry into the ISO 5, resulting in the potential for contamination in the ISO-7 environment to be introduced to the surface of the laminar flow hood and potentially enter finished product during filling manipulations through mechanical transfer.	R2 - Medium	**Reduce risk:** Procedure will explicitly clarify a new sterile wipe must be used to sanitize each component within CAPA-0000040.	Cleanroom Quality Assurance
Hazard ID #	**Process**	**Risk Statement**	**Risk Level**	**Rationale for Acceptance**	
1.B.2	Laminar flow hood	If airflow visualization studies for IV bag filling in laminar flow hoods do not demonstrate unidirectional airflow protection over critical zones during dynamic conditions representative of actual operations (e.g. operators moving faster than challenged in smoke study), there is potential to negatively impact airflow resulting in air contaminants potentially entering finished product.	R2 – Medium	There are multiple controls in place, however human factors impact this failure (e.g. operator moving too fast). Additional enhancements for strength of current controls will be implemented in CAPA-0000040 (e.g. use smoke in training under FRM.TD.1603.H for each operator).	

Corrective and Preventive Actions

Nephron has taken this as an opportunity to strengthen aseptic practices, reinforce operator training, and clarify procedural language where needed. Corrective and preventive actions are in process with effectiveness verification to follow. Key enhancements include:

CAPA-0000054 due December 30, 2025 (Attachment 27):

- Update training program, specifically FRM.TD.1603.H ,*OJT Certification – 503B Filling – General Aseptic Operations* (Attachment 23), to incorporate smoke study demonstrations into aseptic training. Smoke-based training module will be implemented to visually demonstrate airflow patterns and the impact of operator movements on first air
- Effectiveness verification will be confirmed through post-training assessments where operators must demonstrate understanding of unidirectional airflow principles. Direct observation of aseptic techniques during simulated or real tasks ensures 100% compliance with airflow protection practices, such as avoiding obstruction of first air and minimizing unnecessary movement.

CAPA-0000040 due October 10, 2025 (Attachment 90):

- SOP.CM.4930, *Manual IV Bag Filling Operations* (Attachment 16) procedure will be revised to restrict trash removal to defined pauses or post fill only.
- SOP-SC-MB-4509, *Aseptic Techniques* (Attachment 16) will be updated to explicitly clarify a new sterile wipe must be used to sanitize each component
    - Retraining operators, quality assurance and EM staff on best practices (e.g., wipe usage, deliberate movements, door handling).

OBSERVATION 1 C:

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and written.

C. Your firm's media fill program does not ensure simulations are representative of routine commercial operations or worst-case conditions.

1. Media fill protocols and executed records simulate critical interventions only "at least once" rather than at a representative number, type, complexity, and frequency justified by actual production history. This reduces the intervention load and fails to reflect worst-case conditions.

2. Routine production batch records do not consistently document type, frequency, and timing of interventions, including non-routine/unplanned interventions, preventing data-driven justification of media fill design.

RESPONSE 1.C:

The media fill program does ensure simulations are representative of routine commercial operations and worst-case conditions by simulating intervention types, frequency, and complexity representative of production. This observation concerning media fills is written as being applicable to both operations: "Sterile Drug Manufacturing & 503B Outsourcing Facility." As discussed during the inspection close-out meeting on 8/22/2025, this observation only concerns 503B Outsourcing media fills which occur in the laminar flow hood. Media fills for Sterile Drug Manufacturing are not referenced in this observation. The

investigators stated they would revise Observation 1.C to indicate it is only applicable to the 503B Outsourcing Facility, however the change was not made.

Additionally, Observation 1 is indicated as a "repeated observation" from inspections performed 11/2023 – 02/2023 and 01/29/2024 – 02/09/2024. As noted, Observation 1 is applicable only to the 503B Outsourcing Facility. However, the FDA inspection which occurred 01/29/2024 – 02/09/2024 was limited to the Sterile Drug Manufacturing facility, meaning 2025 Observation 1 concerning the 503B Outsourcing Facility could not be a repeat. Additionally, the observation in the Form FDA 483 issued following the 11/2022 – 02/2023 inspection of the 503B Outsourcing Facility referred specifically to validation of aseptic processes which is not repeated in the 2025 Form FDA 483.

Immediate Actions:

During the inspection on 8/21/2025, an intervention assessment was provided to investigators which included intervention data from media fills and production lots. The intervention data confirms media fills include more planned and unplanned interventions than commercial production. The data support media fill studies for manual IV bag filling are representative of the worst-case scenario for commercial production. This information was provided to investigators on 8/21/2025, and discussed in detail with an investigator on 8/22/2025.

During discussions with an investigator on 8/22/2025, it was clarified the intervention documentation process for routine production for both BFS and Automated Syringe Filling ("BART") processes are consistent and in a log format, and the data are trended to support the media fill program. It was also discussed the intervention documentation through batch record notes was only applicable for the manual IV bag filling process, which was acknowledged by the investigator.

There is a consistent process for documenting intervention type, frequency, and timing during routine production, which is used for data-driven justification of media fill design for aseptic processes at Nephron. The only aseptic process does not have an intervention log to consistently document unplanned interventions is the manual IV bag filling in a laminar flow hood.

We would like to clarify a misinterpretation regarding the frequency of interventions performed during media fills.

Interventions are performed more than "at least once" during media fills. The intervention form used during media fills for manual IV bag filling, FRM.CM.1604.D, *Aseptic Process Simulation-IV Bag Intervention Form* (Attachment 25), lists each planned intervention type once for documentation purposes. However, as outlined in the respective media fill protocols, two or more operators participate in each media fill, and each operator executes the full set of planned interventions. As such, each planned intervention is performed multiple times. While this repetition is not individually itemized on the form, it is executed as part of the media fill protocol and verified through batch records and operator sign-offs.

Additionally, inherent interventions occur naturally and frequently during aseptic processing are not simulated separately, as they are inherently represented throughout the process. These are not repeated multiple times on the intervention form, as these activities do not require planned simulation, as they occur throughout the process and are documented in batch notes.

We acknowledge the format of the intervention documentation may have contributed to the misunderstanding, and we are implementing corrective actions to make the frequency and coverage of interventions more transparent in future media fills.

An internal investigation (DEV-0000117 Investigation Finding: Deviation to Media Fill MPL 7.4.1 for Laminar Flow Hood) was initiated to address the concerns regarding intervention trending and documentation during media fills and routine production. The investigation concluded the media fill intervention form does not clearly convey the total number of times each intervention is performed because it does not include a log for inherent/unplanned interventions. The absence of documentation for inherent interventions contributed to the overall perception of limited intervention frequency. Based on these findings, a corrective action plan was developed to address the identified gaps and improve transparency.

The investigation also concluded for routine production (for manual IV bag filling), the method for documenting interventions in batch record notes is difficult to trend, as there is no defined log in place. Therefore, a corrective action plan was developed to enhance the method of documenting interventions during routine manual IV bag filling. Specifically, interventions will be documented in a log format. This format will support data-driven justification of the media fill program and to ensure media fills remain representative of the aseptic process.

Impact Assessment:
There is no impact to marketed product, as media fill studies are representative of the worst-case scenario, including the type and number of interventions occur during production, and the media fill data support the capability of the aseptic process and the appropriateness of validated interventions.

Forty-one (41) batch records of IV bag commercial production lots, produced since the beginning of 2025, were manually reviewed to determine the intervention frequency during routine production. This information was compared to the most recent media fill intervention frequency, and the intervention frequency in media fills was representative of the worst-case scenario, as all intervention types were challenged at a greater frequency than they occurred during any of the production lots reviewed. The data demonstrate manual IV bag media fills simulate production and represent the worst-case scenario by exceeding the number of interventions performed during production. The aseptic process simulations are considered fully representative of the manual IV bag filling process.

Corrective and Preventive Actions (CAPA-0000038 due October 10th, 2025 & CAPA-0000037 due October 23th, 2025) (Attachment 28):
To address this observation and prevent recurrence of inspection misinterpretation, the following corrective actions will be completed:

Procedure Revisions will be captured under CAPA-0000038, *Procedure Updates Related to Intervetion Documentation and Trending* (Attachment 28), due October 10, 2025.

- MPL-SC-MB-0111, *Aseptic Process Simulation - Media Fill - Master Plan* (Attachment 29), will be updated to include details regarding intervention trending for manual IV bag filling.
- The media fill planned intervention form, FRM.CM.1604.D, *Aseptic Process Simulation-IV Bag Intervention Form*, (Attachment 25), will be updated to include a log for documenting inherent and unplanned interventions.

- SOP.CM.4930, *Manual IV Bag Filling Operations Procedure*, (Attachment 17) will be updated to include the list of interventions and describe how each event should be documented during routine production operations.

Intervention Documentation Enhancements will be captured under CAPA-0000037, *Development of Intervention Log for Manual IV Bag Filling* (Attachment 28), due October 23, 2025.

- The method for recording interventions for manual IV bag filling will be updated. A formal intervention log for IV bag filling will be integrated the Electronic Batch Record.

In conclusion, the review of production batch records and media fill data confirms media fills effectively simulate worst-case aseptic conditions, including frequency of planned and inherent interventions. While current practices are adequate, the improvements described above to intervention documentation enhance transparency and support continuous improvement in alignment with regulatory expectations.

OBSERVATION 1 D:

You have not demonstrated in your disinfectant efficacy study that your established contact time of two (2) minutes for sterile 70% isopropyl alcohol used as a disinfectant in your facility is capable of decontaminating nitrile surfaces. Nitrile gloves are primarily used for operating within the ISO-5 and ISO-7 cleanroom environments where sterile drug products are manufactured.

RESPONSE 1 D:

An internal investigation (DEV-000123, *Inspection Finding for Disinfectant Efficacy Study*) determined the nitrile surface type was not present in Nephron disinfectant efficacy studies because regulatory guidance does not currently indicate testing for sterile single-use surfaces. In accordance with USP <1072>, *Disinfectants and Antiseptics*, materials are part of the disinfection program, routinely exposed to disinfectants, and reused in the cleanroom environment should be subject to disinfectant efficacy study. The materials/surfaces in the classified areas at Nephron are routinely exposed to disinfectants as part of disinfection program have been included in disinfectant efficacy studies. The sterile nitrile gloves used in aseptic manufacturing are gamma-irradiated and come with a Certificate of Irradiation and Sterility Assurance Level (SAL 10^{-6}). This validated sterilization process ensures the gloves are sterile prior to introduction into classified areas.

According to SOP-SC-PR-4510, *Sanitization and Transfer of Parts to a Classified Environment*, (Attachment 20) new cleanroom items/material must undergo microbiological assessment prior to use. If a material requires a disinfectant efficacy study according to a microbiology assessment, then a microbiology method validation protocol is initiated. The protocol is written based on the general requirements for microbiology method validations listed in MPL-SC-MB-0110, *Microbiological Test Method Validation Master Plan* (Attachment 91). Clearly defining the differences and testing between materials which undergo disinfection compared to materials which undergo antiseptic sanitization will strengthen the existing program and will be undertaken within CAPA-0000042. Additionally, the master plan detail will be enhanced with regard to assessment of new or modified cleanroom materials and validation of disinfectants and sanitizers. A matrix of materials and chemical agents have been evaluated as a part of the disinfection and sanitization program will also be presented within the master plan.

While a disinfectant efficacy study for disposable glove material was not performed, the observation has been determined to have no impact on product quality or patient safety because personnel monitoring is

conducted for each operator involved in aseptic operations and trending confirms the system is in control. Nevertheless, this observation highlights an area for improvement in the current validation procedure for microbiology test methods. The observation also serves as an opportunity to strengthen our assurance of contamination control and further align our practices with evolving regulatory and industry expectations by performing glove-specific aseptic hand cleaning efficacy studies. In response, a corrective action has been initiated to strengthen the process.

Immediate Actions:
During the inspection from August 11, 2025 to August 22, 2025, when asked about the nitrile material, Nephron indicated the nitrile gloves are single use disposable materials weren't required to be assessed as a part of the disinfectant efficacy study. At no point during the inspection prior to the receipt of this Form FDA 483 observation did the inspectors ask Nephron SMEs any questions or express any concerns with the rationale for this approach to the disinfectant efficacy study. Additionally, Nephron indicated new materials brought into the cleanrooms during maintenance or construction are assessed as a part of the equipment/process changes are opened to for the changes/updates to processes. It was also explained a representative surface testing for the disinfectant efficacy of nitrile surface exists. At the inspector request, chemical compatibility of silicone with disinfectant, standard operating procedures speak to the use of disinfectants, and the most recent disinfectant efficacy study were provided.

Impact Assessment:
There is no potential impact to product safety, identity, strength, purity, or quality (SISPQ) as a result of this observation. Nitrile gloves utilized by Nephron are single-use and sterile. Antiseptic hand cleaning occurs regularly throughout all processes in the ISO 5 and ISO 7 areas per SOP-SC-MB-4509, *Aseptic Techniques*. USP <1072> and EU Annex 1 (2022) do not mandate every surface needs to be tested for disinfectant efficacy and allows for representative or worst-case surface material testing for disinfectant efficacy study. Nitrile gloves are non-porous material similar to polymeric surfaces (PVC, polypropylene, epoxy resin) already included in the disinfectant efficacy study performed by Steris (Attachment 30). Based on the existence of representative surfaces, the disinfectant efficacy of nitrile is reasonably assured.

Routine personnel and environmental monitoring are performed according to SOP-SC-MB-4511, *Environmental and Personnel Monitoring* (Attachment 18), and alert and action levels are established for all microbial monitoring. All action limit excursions are investigated to determine the root cause per SOP-SC-MB-6204, *Microbial Excursions and Deviations* (Attachment 31). Personnel monitoring and environmental monitoring results are trended on a bi-weekly and quarterly basis to assess contamination controls and identify adverse trends. The efficacy of the current antiseptic hand cleaning process and detection of microbial contamination of the sterile nitrile gloves is demonstrated through personnel and environmental monitoring data for the facility.

Contamination recovery rates (CRR) in ISO 5 and ISO 7 environments were assessed over a 24-month period, based on historical environmental monitoring data (Attachment 32). USP <1116>, *Microbiological Control and Monitoring of Aseptic Processing Environments*, recommends maintaining a contamination recovery rate of <1.0% for ISO 5 areas and <5.0% for ISO 7 areas. The environmental monitoring CRR for the reviewed period is 0.09% for ISO 5 samples. The CRR for ISO 7 areas is 0.34%.

Contamination recovery rates (CRR) in ISO 5 and ISO 7 environments were also assessed over the same timeframe, based on historical results from nitrile glove fingertip sampling (Attachment 33). The CRR for ISO 5 glove sampling is 0.03%. The CRR for ISO 7 glove sampling is 0.31%. The CRR for both ISO 5 and

ISO 7 environmental and personnel monitoring results are below the ISO 5 limit recommended by USP. The trending data demonstrates the efficacy of the contamination control strategies, including the antiseptic hand cleaning process, practiced by Nephron.

Corrective and Preventive Actions (CAPA-0000042 Completion of Sanitizer Efficacy Study for Nitrile Gloves due December 12th, 2025) (Attachment 34):

We recognize this observation as an opportunity for continuous improvement. By performing glove specific antiseptic hand cleaning efficacy studies and enhancing our procedures, we can strengthen our assurance of contamination control. The following corrective and preventative actions will be employed to demonstrate Nephron commitment to patient safety and to further align our practices with evolving regulatory and industry expectations.

1. The efficacy of 70% sterile IPA to reduce microbial contamination of nitrile gloves will be validated by performing hand sanitization studies. The studies will challenge the reduction of commonly reported in-house isolates on nitrile singe use gloves according to the EU hand sanitization guidelines in EN1500/12791 validation.
2. Document MPL-SC-MB-0110, *Microbiological Test Method Validation Master Plan* (Attachment 91), will be revised to detail the evaluation required for disinfectant efficacy study applicability when assessing new or modified cleanroom materials. Additionally, the master plan will specify requirements for validating disinfectants and sanitizers, as well as a matrix of materials and chemical agents have been evaluated as a part of the disinfection and sanitization program.
3. Training and awareness will be performed on the updated process following completion of SOP revisions according to SOP-SC-TD-1610, *Training Program* (Attachment 35).

OBSERVATION 2 A:

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

A. Your firm failed to establish and implement an adequate environmental monitoring (EM) program that includes all critical surfaces and locations within classified areas.
For example, but not limited to, your firm's EM program does not include sampling of the operator contact portion of the barrier on the Bausch 515 Automated Syringe Filler in Room 282G(BART) Syringe Filler (Equipment ID/NID # NOF-01117) Cap Barrier and Syringe Barrier during aseptic operations. These surfaces are also excluded from your firms cleaning and disinfection program, despite its direct contact with operators and proximity to the ISO 5 critical zone.
Your firm failed to ensure that all high-risk and frequently touched surfaces in classified areas are routinely monitored and disinfected to detect and prevent microbial contamination. These deficiencies in the environmental monitoring and cleaning program create an unacceptable risk of undetected microbial contamination of sterile drug products administered directly to patients' cardiovascular system. The lack of effective contamination control undermines sterility assurance and patient safety.

RESPONSE 2.A:

An internal review confirmed all critical surfaces and locations within classified areas are routinely monitored and included within the cleaning and disinfection program. Nephron disagrees any perceived deficiencies in the environmental monitoring and cleaning program create "an unacceptable risk of undetected microbial contamination of sterile drug products administered directly to patients' cardiovascular system." As was explained multiple times during the inspection, the BART syringe filler is not commercially active and is currently under qualification. On-site inspectors expressed concern for the outside of operator sterile sleeves may touch the bottom of the barrier surrounding the cap addition zone following review of dynamic airflow visualization study video. Those areas are identified in the image below.

Figure 2.A-1: 282G-1 Cap Addition Shroud Locations



Based on the angle of the smoke study video, confirmation of physical contact cannot be definitively determined. However, the inspectors repeatedly declined Nephron offer to view operation of the updated BART machine design in-person. The BART syringe filler (Equipment ID / NID # NOF 0117) operation has been observed by Nephron SMEs during multiple Gemba walks conducted as part of Design Failure Modes and Effects Analysis (DFMEA), Process Failure Modes and Effects Analysis (PFMEA), and environmental monitoring performance qualification (EMPQ) risk assessment design, and contact with the

cap addition shroud barrier was not observed. Although it has not been observed, it is feasible contact with the barrier could be made.

Currently, cleaning and disinfection of the room 282G syringe filler cap addition shroud barrier occurs according to WRK-SC-SR-4530-K, *Cleaning/Sanitizing Automated Filling Suites* (Attachment 36). Step 1.1.2.c specifies the cleaning and disinfection process for cleaning the shroud and step 1.1.2.g details cleaning external panels of the filling machine. The process for drafting and executing environmental monitoring performance qualifications (EMPQ) selection of sample sites within a cleanroom are described in SOP-SC-MB-4542, *Environmental Monitoring Performance Qualification Process* (Attachment 37) and WRK-SC-MB-4542-A, *Instructions for drafting Environmental Monitoring Performance Qualification* (Attachment 38).

Per SOP-SC-MB-4542, *Environmental Monitoring Performance Qualification Process*, risk assessments are performed to determine EMPQ sample sites through assessment of potential "critical points", defined in WRK-SC-MB-4542-A, *Instructions for drafting Environmental Monitoring Performance Qualification* as:

- A location where a process step occurs if contamination is present, would impact the purity, efficacy, or safety associated with product produced in the suite, or
- A location represents an area is likely to have contamination due to frequent contact by operators or materials, a high level of operator traffic, or is difficult to routinely sanitize or clean effectively.

Additional factors considered per SOP-SC-MB-4542, *Environmental Monitoring Performance Qualification Process* include (but are not limited to) proximity to open product or product contact surfaces and activities associated with interventions. Each critical point is then scored to determine the associated risk, which informs decisions related to sample sites.

A risk assessment was performed as part of the environmental monitoring performance qualification PQ-464C, *Addendum to Environmental Monitoring Performance Qualification for Suite 282 (BART)* (Attachment 39) for the determination of sample sites for environmental monitoring (EM) for the BART syringe filler (Equipment ID / NID # NOF 0117) and the 282 Manufacturing Suite. The following sites were determined applicable during Phase I of the EMPQ for the cap addition shroud following risk assessment:

- Contact Plate: Inside left of cap addition shroud
- Swab: Inside cap addition tool scoop
- Swab: Inside cap addition tool handle loop
- Surface Air Sample and Settle Plate: Under cap addition shroud below cap addition port

The hazard surrounding potential operator contact of the bottom edge of the cap addition shroud is preliminarily assessed below with the same structure applied in PQ-464C, *Addendum to Environmental Monitoring Performance Qualification for Suite 282 (BART)* which contains the description of the personnel, material, and process flows in Suite 282. Risk ranking criteria is aligned with SOP-SC-QA-1154, *Risk Management* (Attachment 40), with granularity for the applicable process described within PQ-464C, *Addendum to Environmental Monitoring Performance Qualification for Suite 282 (BART)*. For ease of review, a scoring rationale column is additionally provided to provide context for the risk analysis.

Table 2.A-1: Overview of Hazards Identified in Risk Based-Impact Assessment

Hazard	Potential Failure Mode (Hazard)	Potential Failure Effects	SEVERITY (S)	Potential Causes	OCCURRENCE (O)	DETECTION (D)	RPN	Scoring Rationale
Bottom Edge of Cap Addition Shroud 3	Personnel contact increases potential for microbial contamination on surface	Contamination of edge of edge of primary engineering control	4	Personnel/material contact, insufficient sanitization of the primary engineering control.	2	2	**16**	S- Site is part of the primary engineering control. There is a serious risk to patient safety and product quality as a result. O- EMPQ is being utilized to assess the state of the room. Sample site is assumed could occur at some point until data can be collected in Phase II. Inadequate sanitization could lead to an increase in microbial build up at this site. Personnel are frequently present in the area wearing sterile gloves and sleeves and contact with the site is feasible. Material is both sanitized (outer packaging) and sterile (inner component and autoclaved cap addition tool) within this area. Direct contact with the site is not expected for operation, but possible. D- Multiple sites exist along the process path including swab sampling, personnel monitoring, surface testing, and continuous viable air testing. Trending for data collected within the area is performed and any contamination within the area is likely to be detected by sampling within the same area performed within 12 inches of the sample location. Product testing for product filled in the room would provide a pathway to detect contamination in the absence of room monitoring.

Along with the risks identified through the PQ-464C, *Addendum to Environmental Monitoring Performance Qualification for Suite 282 (BART)* risk assessment, this hazard will be integrated within the PFMEA conducted within QRM-503B-25-002 *Bausch 515029 Filling and Closing Machine Process* for lifecycle management through the Quality Risk Management program.

3673

By design, operators within BART do not touch critical surfaces during operations according to SOP.CM.4924, *Operation of the Bausch 515 Filling and Closing Machine,*(Attachment 8) section 17.2.2.2. The new BART design and resulting process involves the use of autoclaved tools to add components into the machine per SOP.CM.4924, *Operation of the Bausch 515 Filling and Closing Machine,* Attachment 5. Autoclaved parts are transferred into the machine according to SOP.CM.4924, *Operation of the Bausch 515 Filling and Closing Machine,* section 9.1. The cap addition shroud barrier is separated from the manufacturing shroud of the Bausch 515 Automated Syringe Filler in Room 282G(BART) (Equipment ID/NID # NOF 0117) where sterile product is exposed during filling operations. These areas within the new barriers for component addition are classified as ISO 5, in addition to the separate main barrier. Handles were designed in accordance with the Bausch 515029 Design Failure Modes and Effects analysis (DFMEA) to ensure the critical surface which touches the components does not require contact and does not block airflow for use. The main barrier, which separates component addition from the filling zone, is only accessible through glove ports during operations in the revised BART process in accordance with standard operating procedure SOP.CM.4924, *Operation of the Bausch 515 Filling and Closing Machine,* steps 18.1.2 and 18.1.3. All frequently contacted surfaces are sanitized every 30 minutes during operations, per SOP.CM.4924, *Operation of the Bausch 515 Filling and Closing Machine,* step 20.2.2 "During the 30-minute glove check, the frequently contacted surfaces within the room and the machine shall be sanitized."

Alert and action levels are established for all microbial monitoring according to SOP-SC-MB-4511, *Environmental and Personnel Monitoring* (Attachment 18). The action limit for the ISO-5 area is ≥1 colony forming unit (CFU) and all recoveries in ISO 5 areas are investigated to determine the root cause of the environmental monitoring (EM) excursion per SOP-SC-MB-6204, *Microbiological Excursions and Investigations* (Attachment 31). The ISO 5 manufacturing suite 282 data from 08-2024 to 08-2025 was reviewed for contamination recovery rate (CRR) (Attachment 41 – 282 Suite CRR Viable Trend), and the ISO 5 area including 282G and 282G-1 had zero (0) recoveries out of 1403 samples for a CRR of 0% which is within the limit of <1% per USP <1116>. This demonstrates the area is within a state of control.

We recognize this observation as an opportunity for continuous improvement and the hazard identified will be added to the current PFMEA in progress for life-cycle review.

Immediate Actions:

During the inspection on August 13, 2025, and several days thereafter, Nephron clarified the BART syringe filler is not commercially active and is currently under qualification. The completed risk assessment for the environmental monitoring performance qualification (which considered personnel, material, and process flow) was provided to inspectors on 8/13/2025, in addition to the Quality Risk Management Plans for the Design Failure Modes and Effects Analysis (DFMEA) and the Process Failure Modes and Effects Analysis (PFMEA). The risk analysis phase of the DFMEA was completed prior to smoke study execution and the PFMEA remains in-progress to ensure all hazards identified through design and process challenges are captured within the risk assessment.

OBSERVATION 2 B:

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

B. Your firm's personnel monitoring program does not include all areas of the gown or body that may contact critical surfaces during operations. For example, the operator's forearm, identified by your firm as a frequent recovery site, is not routinely sampled when loading caps on the Bausch 515 Automated Syringe Filler (Equipment ID / NID # NOF 01117) in Room 282 (BART Syringe Filler). Your firm failed to established and follow an adequate personnel monitoring program designed to detect contamination on high-risk operator surfaces in proximity to aseptic operations. For example, during review of smoke study footage for the Bausch 515 Automated Syringe Filler (Equipment ID / NID # NOF-01117) in Room 282G (BART Syringe Filler) at time point 43:03-43:04, we observed the top of the operator's forearm contacting the underside of the operator contact barrier, which separates the operator from the ISO 5 critical zone. This location is not included in your firm's routine personnel monitoring program.

Your firm's management acknowledged that the forearm is a common recovery site of objectionable organisms. Despite this, your personnel monitoring program does not include routine sampling of this point on the forearms, and the contact surface itself is excluded from your environmental monitoring and cleaning programs.

Your firm failed to implement an adequate personnel monitoring program to identify and control microbial risks associated with operator interactions at the barrier system. These deficiencies create an unacceptable risk of microbial contamination to sterile drug products and undermine sterility assurance and patient safety.

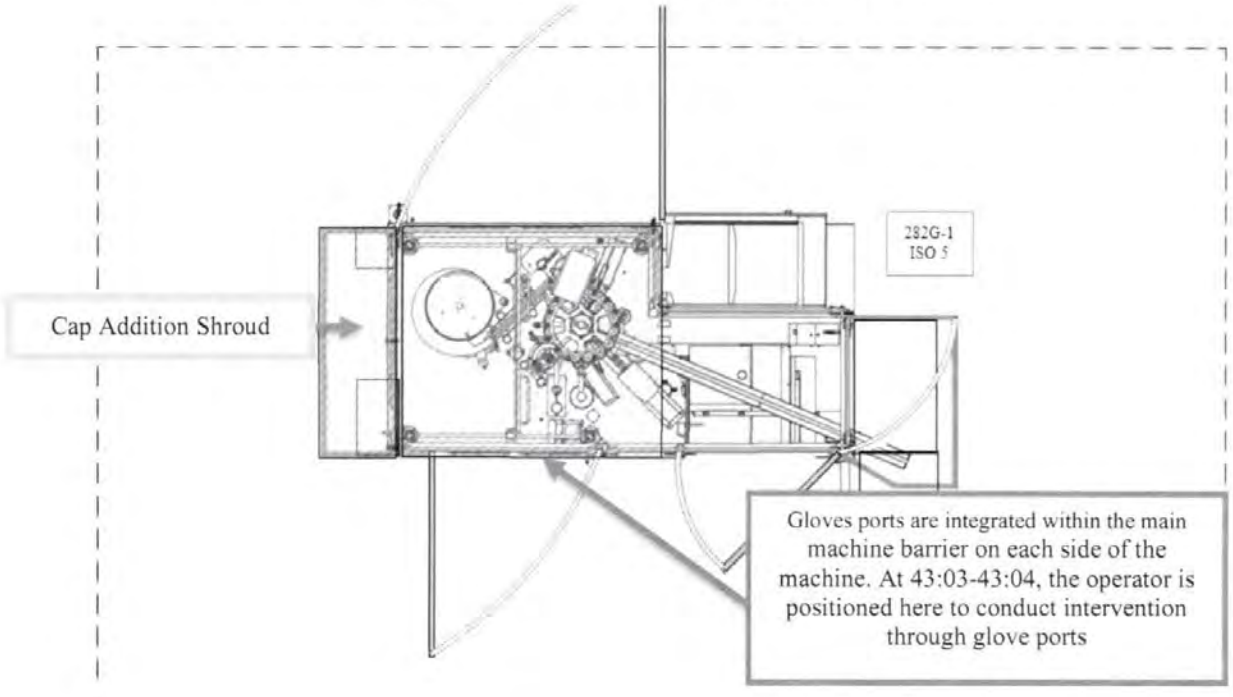
RESPONSE 2B:

Nephron disagrees with any perceived deficiencies in personnel monitoring "create an unacceptable risk of undetected microbial contamination of sterile drug products administered and undermine sterility assurance and patient safety" as BART is not currently used in commercial production as it is currently under qualification. Following review of dynamic airflow visualization study video, the inspectors expressed concern for the outside of operator sterile sleeves may, theoretically, touch the bottom of the barrier surrounding the cap addition shroud while loading caps. However, Nephron does not believe this concern is reflected in at the timepoint referenced in this observation (43:03-43:04) as no operator was present in the cap addition shroud. An intervention was occurring through glove ports at this time which could not result in contact to the underside of the operator contact barrier (see images below).

Figure 2.B-1: Smoke Study Video Provided at 43:04



Figure 2.B-2: Overview Map of 282G-1



Operators are within cap introduction shroud at timepoints 33:53- 34:32 in the provided smoke study video. As noted in response to observation 2.A, based on the angle of the smoke study video, confirmation of physical contact cannot be definitively determined.

Additionally, the inspectors repeatedly declined Nephron offer to view operation of the updated BART machine process in-person.

Personnel monitoring locations currently include the following locations:

- Right sterile glove fingertips
- Left sterile glove fingertips
- Inside forearm of right sterile sleeve
- Inside forearm of left sterile sleeve
- Chest – zipper of gown
- Top of hood
- Side wall of goggles where strap connects

These sites were determined through a Personnel Monitoring Program Assessment prepared for the previous BART process, prior to the addition of the two new shrouds for component addition. Through this assessment, the involvement of cleanroom personnel was assessed per each applicable process and personnel monitoring site locations on the gown of operators were determined. In order to dispense caps in the previous process, the aseptic machine operator forearm and glove entered the environment within the 515029 machine, as there was only one barrier around the filling operation in the previous process. The operator sterile gloves and sterile sleeves now only enter the new component addition ISO-5 shrouds and no operator gowning enters the area where sterile product is exposed during filling operations. The monitoring sites determined based on the previous process are still applicable and appropriate to the new process because operator sterile gloves and sleeves enter the component addition shrouds, however additional protection is provided for the filling process because it is now physically separated from operator gowning and only accessible through integrated glove ports during production operations.

Per PQ-464C *Addendum to Environmental Monitoring Performance Qualification for Suite 282 (BART)* (Attachment 39) and the Personnel Monitoring Program Assessment, personnel operating within the ISO 5 515029 BART filling machine, prior to leaving the cleanroom suite or upon conclusion of operations, must perform personnel monitoring on all gown sites listed within the Personnel Monitoring Program Assessment and personnel monitoring of the gloves and forearms prior to doffing gloves and sleeves for any reason.

For clarification, Nephron management did not acknowledge the forearm is a common site for recovery of objectionable organisms as objectionable organisms are **not** frequently recovered from the forearm of BART operators. Since re-design, there have been 0 recoveries from forearms of operators within the ISO 5 282G area. Across the entire site within the last 12-month period, there have been 13 recoveries out of 12099 samples from the forearms in an ISO 5 area for a contamination recovery rate (CRR) of 0.11% which is within the limit of <1% per USP <1116>. This demonstrates personnel monitoring of forearms is within a state of control. Alert and action levels are established for all microbial monitoring according to SOP-SC-MB-4511, *Environmental and Personnel Monitoring* (Attachment 18).

The action limit for the ISO-5 area is ≥1 colony forming units (CFU) and all recoveries in ISO 5 areas are investigated to determine the root cause of the environmental monitoring (EM) excursion per SOP-SC-MB-6204, *Microbiological Excursions and Investigations* (Attachment 31).

Immediate Actions:

During the inspection, Nephron clarified the BART syringe filler is not commercially active and is currently under qualification. The completed risk assessment for the environmental monitoring performance qualification was provided to inspectors on 8/13/2025 in addition to the Quality Risk Management Plans for the Design Failure modes and Effects Analysis (DFMEA) and the Process Failure Modes and Effects Analysis (PFMEA). The risk analysis phase of the DFMEA was completed prior to smoke studies.

OBSERVATION 3.1:

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed.

Specifically,

3.1 You have failed to determine root cause and implement effective corrective action for cracked media plates used for environmental monitoring (EM) analysis. You first identified this issue on 02/14/2024, where it then became an ongoing issue. In February of 2025, you initiated and closed a Corrective Action/Preventative Action (CAPA) without determining the root cause. Since closure of the CAPA, you have generated approximately nine (9) additional cracked plate events. Additionally, during 02/14/2024-02/25/2025 you generated approximately 87 events where you discarded media plates largely to include personnel monitoring samples that were collected to document the environmental conditions for media fills and the production of sterile drug products.

RESPONSE 3.1:

This Observation is specific to the 503B Outsourcing Facility and is referenced as a "repeated observation from the inspection performed 01/29/2024 – 02/09/2024." However, the Form FDA 483 issued in February 2024 did not include any observations related to a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications (21 CFR § 211.192). An internal review confirmed corrective and preventive actions have been put into place following investigations related to cracked media plates used for environmental monitoring (EM) analysis. Quality Event Project Record, PR# 1031030 (Attachment 42) was initiated for a damaged personnel monitoring (PM) sample had been submitted to the Microbiology Laboratory with damage to the surface of the agar. The event identified sampling technique was the root cause of the event. Based on this finding, Corrective Action/Preventive Action (CAPA) projects 1031440 and 1031442 (Attachment 43 and 44) were initiated to add supplemental oversight to the program and create a sampling visual aid which is captured in a work instruction document, WRK-SC-MB-4511-I, *Personnel Monitoring Work Instruction* (Attachment 45). After implementation, the occurrence rate of damaged plates being submitted to the laboratory decreased. Refer to Attachment 46 (CAPA Summary Table). Based on these findings, the ability to prevent and detect cracked plates prior to incubation has been effective as evidenced by the low rate of occurrence.

In response to the 87 events where plates were submitted to the laboratory damaged, the topic was escalated to Microbiology and Quality Assurance Management, and quality events were initiated to investigate the samples. The samples were not processed for incubation per WRK-SC-MB-6220-C, *Sample Incubation Decision Tree,* Version 1.0, Section 1.2.1 which stated, "Samples that are significantly damaged, mishandled, or exposed to non-cleanroom conditions should not be incubated." During the investigations opened for these events, assessments were conducted per SOP-SC-QA-1220, *Deviations and Investigations.* The impact for each sample was assessed based on the sample type, role of the technician if the samples were personnel monitoring, and proximity to the aseptic process. A summary of these events was provided in Action 254 during the inspection (Attachment 47).

The incubation process was updated in February 2025 to process all samples for incubation regardless of damage to the agar, and the sampling process was updated to instruct personnel to inspect samples in the cleanroom and re-sample in the event damage is observed. Both the original sample as well as the additional sample are retained and processed through incubation. These updates were captured in SOP-SC-MB-4511, Environmental Monitoring, version 49.0.

Nephron acknowledges there have been nine (9) additional observations of cracked media plates since implementation of these corrective actions. In response to this observation, an investigation was opened under DEV-0000124 to complete an evaluation of historical events to review the occurrences and conduct a holistic investigation to determine root cause and an impact assessment. Through investigation it was determined corrective actions have been effective at reducing the observations of damaged plates being submitted to the Microbiology Laboratory for incubation. While this is the case, additional corrective actions have been put into place through procedural revisions as outlined above. At this time, any observation of damaged samples is escalated per SOP-SC-MB-6220, *Environmental Monitoring Incubation and Enumeration (Attachment 48)* and WRK-SC-MB-6220-C, *Sample Incubation Decision Tree (Attachment 49)*. This ensures visibility and investigation into these events as necessary.

Immediate Actions:

On August 19, 2025, Nephron provided documentation to the investigator demonstrating the decrease in events of plates identified to be damaged prior to incubation. Refer to Action 254 (Attachment 47). This documentation included a spreadsheet which detailed the root cause and conclusion of impact assessment for each investigation conducted. A storyboard presentation, in PowerPoint format, describing each event was provided to the investigators.

As a result of these investigations, multiple corrective and preventive actions were put into place to mitigate the occurrence of damaged plates. These corrective actions, detailed in the storyboard, and provided within Action 254 to the investigator, demonstrated the decrease in number of events from February 2024 through August 2025. These documents were discussed with the Nephron SME on August 19, 2025.

During investigation (DEV-0000124), two root causes were identified. The first, a gap was identified in the robustness of media qualification, and lack of clarity for the sample transport process. Remel media has not been sufficiently challenged for extended LFH exposure or storage in the cleanroom once opened. While QC testing including sterility and growth promotion testing confirmed baseline suitability, the media has not been sufficiently challenged for extended LFH exposure, opened sleeve storage.

The second root cause was identified that the CAPA actions from CAPA PR# 1032568 were not effectively implemented to prevent damage of samples during transport to the Microbiology laboratory after sampling prior to incubation.

Impact Assessment:
The impact of these deficiencies is limited to environmental monitoring results and does not extend to product quality. Since February 2025, all plates, including those with visible damage, have been incubated to ensure recovery of any potential microorganisms and maintain the integrity of environmental monitoring data. No adverse impact to product sterility assurance has been identified, as incubation of all samples provides assurance that microbial recovery would not have been compromised by surface damage to the agar. Contributing factors such as personnel technique during sampling and localized airflow conditions were identified as secondary influences but do not represent systemic gaps in aseptic control.

The samples reported to be damaged prior to 02/14/2025 that were not incubated were assessed through independent investigations and were considered "missing samples". The impact of the missing samples was evaluated through each of these investigations. Those events were evaluated based on the type of sample, location of the sample, and potential impact of that sample on the associated product lot if applicable. After procedural revision on 02/14/2025, all plates, including those with visible damage, were processed for incubation.

From February to August 2025, 112,778 EM samples were collected, with only 9 cracked plate events (0.01%). Sterility assurance and EM program sensitivity were not compromised. The long- and short-term EM/PM trend indicates this remains under the CRR limit required per USP <1116> (CRR <1% for ISO 5 and <5% for ISO 7). Historical results remain valid as QC and growth promotion testing confirmed media suitability.

Corrective and Preventive Actions (CAPA-0000053, *Definition of Sample Transport Process for EM and PM Samples* due October 27, 2025, and CAPA-0000052, *Incorporation of Media Qualification Plan* due December 31, 2025 (Attachment 51 and Attachment 50))

A review of environmental monitoring (EM) media qualification revealed that while key parameters such as hold times, exposure durations, and incubation ranges have been studied and qualified, not all aspects were fully addressed (e.g., opened container storage, desiccation, and moisture loss).

The following commitments will be captured through Corrective Action/Preventive Action CAPA-0000052, and CAPA-0000053:

- MPL-SC-MB-0110, *Method Validation Master Plan*, will be revised to include detailed onboarding requirements for EM media, and a formal qualification protocol will be executed to close the identified gaps. Preventive measures, including a qualification matrix, protocol-driven onboarding of new media, and periodic review, will ensure long-term control. Effectiveness will be verified through documentation audits and trending of EM data post-implementation.
- The transport process will be redefined through procedural updates to clarify storage and transport of samples within the cleanroom.

The Microbiology EM program is used for regular monitoring of the manufacturing environment, surfaces, and personnel on a pre-determined frequency. The EM data collected from these activities are trended on a short-and long-term basis to demonstrate environmental and personnel controls per SOP-SC-MB-6265 (Attachment 52), *Environmental Action Committee*, and SOP-SC-MB-4516, *Environmental Monitoring Quarterly Trend Report* (Attachment 53). Additionally, the EM and Personnel Monitoring (PM) Alert and Action Limits allow responses individual events based on their severity, and each response includes an assessment regarding the impact of these events upon product quality to ensure patient safety. The long and short-term trending of this area and surrounding spaces indicates a contamination recovery rate (CRR) of <1% for ISO 5 spaces, <5% for ISO 7 spaces established by USP <1116>.

OBSERVATION 3.2:

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed.

Specifically,

3.2 You have not determined suitability of your EM sampling process of using settle plates as opposed to RODAC contact plates for performing personnel fingertip monitoring. This change was implemented on 05/14/2025 in response to the cracked/damaged media places on-going issue that was identified 02/14/2024.

RESPONSE 3.2:

The use of 90 mm Tryptic Soy Agar (TSA) plates for personnel monitoring was assessed through Change Record CR# 12505 (Attachment 54), closed on May 17, 2024. The 90 mm settle plates currently used for glove plating were selected for the larger surface area allowing for greater ease of sampling for personnel gloved fingertips, as well as reduce potential for inadvertent contact with the agar during the sampling process. These changes were made to comply with the guidance in the 2022 EU Annex 1, *The Rules Governing Medicinal Products in the European Union Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use*—not "in response in response to the cracked/damaged media plates on-going issue" as stated in the observation.

Immediate Action

During the inspection on August 15, 2025, Nephron provided the documented assessment from QIP-23-001 (Action 199, see Attachment 56), completed August 1, 2024. The EM program was evaluated to identify improvements against industry standards including FDA Guidance for Industry, *Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice*, United States Pharmacopoeia (USP) <797> *Pharmaceutical Compounding – Sterile Preparations*, USP <1116> - *Microbiological Control and Monitoring of Aseptic Environments*, USP <1117> *Microbiological Best Practices*, Parenteral Drug Association (PDA) Technical Report No. 13 – *Fundamentals of an Environmental Monitoring Program*, PDA Technical Report 77 – *The Manufacture of Sterile*

Pharmaceutical Products Using Blow Fill Seal Technology, and EU Annex 1 *The Rules Governing Medicinal Products in the European Union Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use.*

The current PM process aligns with the requirements outlined within the 2022 EU Annex 1, *The Rules Governing Medicinal Products in the European Union Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use.* This change was not made in response to the damage observed during sampling, but rather to complete process improvements as outlined by the assessment provided. Additionally, the events provided in the summary for Action 254 (Attachment 47) associated with the damaged plates also included samples collected using the smaller RODAC style plates, demonstrating the damage is not solely isolated to the use of the 90 mm contact plates.

A rationale document was provided detailing the justification and rationale for use of the 90mm TSA plates for personnel monitoring in Action 199. The documents related to the suitability determination for use of settle plates for gloved fingertips were requested and provided, however were not reviewed or discussed with Nephron during the inspection.

Within the Personnel Monitoring (PM) Program Assessment, it is explained the selection of the 90 mm agar plates was made to mitigate inadvertent contamination during sampling, and reduce the potential the same point on the agar surface is contacted multiple times during the sampling process (Action 199, see Attachment 56). Additionally, within the media assessment provided, the composition of the Settle Plate medium was compared to the RODAC contact plate medium and found to have the same basic composition with exception of the lecithin and polysorbate 80. As the 90 mm plates are only used in personnel monitoring to collect glove samples, there is no need for a neutralizer as gloves are not sanitized with disinfectants leaving cleaning residue.

Impact Assessment

Based on the review of the current media types and sampling process implemented at Nephron, there is no further action required. Rationale for the selection of the 90 mm TSA settle plates was reviewed and found to be sufficient for use in monitoring of personnel gloves. The current process is compliant with the above-mentioned industry standards and practices.

OBSERVATION 3.3:

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

3.3 You inappropriately invalidated a stability sample at T0 for sterility for Provo choline (Methacholine chloride) Solution for inhalation 3 mg/mL Lot #: 324261 Expiration: 07/31/2025. After incubating the SDA canister at 20-25C for one (1) day, you identified turbidity and thereby stopped the incubation process to proceed with subculturing for

microbial identification. After failing to obtain viable growth on the subcultures, your quality unit concluded the turbidity observed die not contain viable microorganisms and ultimately invalidated the original sample without determining root cause of the turbidity. Per your written procedure MTM-SC-MB-6308 entitled, 'Sterility Test Procedure' Revision: 39 effective 18-APR-2025, which is written based on USP <71>, samples are only invalidated for the four (4) reasons:

a. 'The data of the microbiological monitoring of the sterility test environment shows a fault

b. A review of the testing procedure used during the test in question reveals a fault

c. Microbiological growth is found in the negative controls

d. Upon determination of the identity of the microorganisms isolated from the test, the growth of the species isolated may be ascribed unequivocally to faults with respect to the material and/or the technique used in conducting the sterility test.

Per your Director of Microbiology, the invalidated sample did not fall within any of these conditions.

RESPONSE 3.3:

An internal review confirmed the sterility test for Lot#: 324261, Provocholine (methacholine chloride) Solution for Inhalation 3 mg/3 mL (1 mg/mL), Stability station zero-month, semi-permeable room temperature, vertical orientation (0M SRT VERT), was invalidated based on procedure and USP <71> *Sterility Tests*. Per the written procedure, MTM-SC-MB-6308, *Sterility Test Procedures*, Version 39.0, (Attachment 57) which is written based on guidance in USP <71>, the test may be considered invalid only if one of the following conditions is met:

a. "The data of the microbiological monitoring of the sterility test environment shows a fault.
b. A review of the testing procedure used during the test in question reveals a fault.
c. Microbial growth is found in the negative controls.
d. Upon determination of the identity of the micro-organisms isolated from the test, the growth of the species isolated may be ascribed unequivocally to faults with respect to the material and/or the technique used in conducting the sterility test."

The sterility test tryptic soy broth (TSB) canister for Lot#: 324261, 0M SRT VERT, did not complete the required incubation timeframe of NLT 14 days, per USP <71>, and presence of microbial growth was not confirmed; therefore, the event was deemed as a fault in following the test procedure. At the time of the event, management considered the test invalid per condition (b) listed above, which was explained to the inspectors by the Director of Microbiology. This decision prompted a confirmatory testing plan as part of the laboratory investigation, Microbiology excursion report #: NPC-ER-MQC-23-025 (Attachment 58), to repeat a sterility test with the same number of units as used in the original test for Lot #: 324261, 0M SRT VERT. No evidence of microbial growth was found in the repeat test, and the acceptable results were reported for product sterility.

A point of clarification, the FDA 483 Observation 3.3 has a typographical error on Line 3. Line 3 states, 'After incubating the SDA canister at 20-25°C for one (1) day, you identified turbidity…' The impacted canister was a TSB canister. This error has no

impact on the resulting investigation and response following issuance of the Observation 483.

Immediate Actions:

During the FDA inspection on August 18, 2025, Nephron explained the laboratory investigation NPC-ER-MQC-23-025 was closed after multiple subculture attempts confirmed no growth. The anomaly was reported as turbidity due to limitations in the electronic documentation system. Finished product sterility results and retest results from the same lot were provided to auditors in support of the disposition decision. The inspectors observed:

- The investigation was prematurely closed without escalation to perform a manufacturing investigation
- Full characterization of the anomaly was not performed.

Nephron recognizes there was a failure to thoroughly identify the root cause which led to invalidation of the sterility test for Lot#: 324261, 0M SRT VERT. Sterility testing is designed to determine whether there is microbial contamination within product samples purporting to be sterile examined under the conditions of the test. The test procedure by itself is not intended to ensure a batch of product is sterile; however, it is one of many quality attributes to be evaluated prior to product release. Sterility assurance of a batch is primarily accomplished through adherence to established aseptic processing procedures. Nephron acknowledges there was a failure to conduct a thorough review of the aseptic manufacturing processes. A manufacturing investigation should have been immediately initiated upon being alerted to abnormal sterility test results, whether or not the batch had been distributed.

In response to this observation, Nephron opened a new investigation to conduct a thorough, retrospective assessment regarding the deficiencies surrounding this event (DEV-0000125, *Inspection Observation: Inappropriate Invalidation of Stability Sterility Sample*). The investigation focused on the following:

1. Invalidation of the original sterility test due to pre-mature removal of the inconclusive stability sterility test sample from incubation.
2. Misclassification of abnormal particulate within medium as "turbid".
3. Failure to conduct a manufacturing assessment or investigate the root cause of particulate.

Lot#: 324261, Provocholine (methacholine chloride) Solution for Inhalation 3 mg/3 mL (1 mg/mL), Mfg Date: 08/25/2023, Exp. Date: 07/31/2025, was inducted into the Nephron Stability program as part of a Post-Market Stability Study to provide documented evidence and assurance supporting the product approved shelf-life. Finished product release testing for Lot#: 324261, including sterility testing, was completed and all laboratory test results verified to meet specification criteria.

Upon identifying the abnormality during the day one (1) evaluation of sterility test samples for Lot#: 324261, 0M SRT VERT, the TSB canister was promptly removed from incubation and immediately subcultured using various media types (SDA, TSA, and SBA) to confirm or dispute presence of microorganisms. Delaying subculture may compromise microorganism

viability; therefore prompting actions for immediate incubation removal and subculture attempts of the impacted sample. The subcultured plates were incubated for an additional three (3) days, and no microbial growth was obtained. Through the investigation, evidence including photographs, interviews, and subculture results, supported the sample was improperly removed from incubation. Therefore, the sample did not meet the test criteria in accordance with USP <71> and MTM-SC-MB-6308, *Sterility Test Procedures* (Attachment 57). The incident was not a true sterility test out-of-specification. Visible particulate was incorrectly classified as "turbid" during canister evaluations following sterility testing of Lot#: 324261, 0M SRT VERT. This incorrect classification led to premature test termination, an inaccurate OOS alert, and then inappropriate invalidation without proper investigation and root cause determination of the foreign matter, as was explained by the Director of Microbiology during the inspection. Using the 6M root cause analysis tool, material, machine, measurement, and mother nature, in relation to both manufacturing and testing processes, were ruled out as potential root causes. The root cause for the incident which led to the sterility test being invalidated, was attributed to deficiencies in Method. Man was deemed a contributing factor.

Sterility testing is designed to determine whether there is microbial contamination within product samples purporting to be sterile examined under the conditions of the test. The test procedure by itself is not intended to ensure a batch of product is sterile; however, it is one of many quality attributes to be evaluated prior to product release. Sterility assurance of a batch is primarily accomplished through adherence to established aseptic processing procedures. Sample contamination due to foreign particles can occur during the production or testing processes, if procedures are not appropriately established and followed. Review of the manufacturing batch record for Lot #: 324261 does not indicate production processes were not followed. Prior to sterility testing of Lot#: 324261, 0M SRT VERT, the finished product sterility testing and all results met release specifications. Additionally, sterility testing has been completed for Lot #: 324261 at the following additional stability time points: 6-month, 12-month, 18-month, and 21-month expiry, and all results conformed to test specifications. Review of the Quality Complaint Logbook, demonstrated there were no complaints received for Lot#: 324261, or for the other Provocholine stability lots tested on 10/22/2023. There is no potential impact to patient safety as subsequent sterility testing and other release testing specifications were met prior to product release. As an interim control, the currently implemented sterility procedure requires an excursion report to be initiated in accordance with SOP-SC-MB-6204, *Microbiological Excursions and Investigations* (Attachment 31) for any positive sterility result. All positive results require escalation to QA management in daily escalation and review meetings.

Impact Assessment

Sterility testing is one of many quality attributes to be evaluated prior to product release. Sterility assurance of a batch is primarily accomplished through adherence to established aseptic processing procedures. The sterility test is designed to determine whether there is microbial contamination within product samples purporting to be sterile examined under the conditions of the test. The test procedure by itself is not intended to ensure a batch of product is sterile; however, it is one of many quality attributes to be evaluated prior to product release. Sterility assurance of a batch is primarily accomplished through adherence to established aseptic processing procedures. Sample contamination due to foreign particles can

occur during the production or testing processes, if procedures are not appropriately established and followed. Review of the manufacturing batch record for Lot #: 324261 does not indicate any lapses in adherence to production processes. According to the BFS Hazard Failure Mode and Effects Analysis (FMEA) report RA-CCS-NPC-24-001-R1, performed as part the Contamination Control Strategy, potential failure modes and causes associated with the potential failure effect of Particle Contamination were evaluated as part of the investigation. Upon evaluation of each mode and cause, it was determined that there was no evidence of the presence of any failure mode during production of Lot#: 324261 which would have generated or increased the risk of the generation of particulate matter during filling operations. Finished product release testing for Lot#: 324261, including sterility, met all test specifications. All tests performed throughout the stability study, and up to expiry, have yielded results that met specifications. Sterility testing has been completed thus far for Lot #: 324261 at the following additional stability time points: 6-month, 12-month, 18-month, and 21-month expiry. Review of the Drug Product Quality Complaint Logbook demonstrated there were no complaints related to microbial or particulate contamination received for Lot#: 324261, the other Provocholine stability lots tested on 10/22/2023, nor for the Provocholine Kit Lot into which this component lot was packaged (Lot#: 373401). Additionally, a Retain Inspection of three (3) outer cartons from Kit Lot#: 373401 was performed on 08/12/2024 in accordance with SOP-SC-QA-3251, Version 14.0, *Finished Product Annual Examination of Retained Samples*, and no defects were identified for any vials within these outer cartons. A historical review of the past two (2) years of sterility test results indicate besides this event, there was only one sterility failure reported, which was invalidated because upon determination of the identity of the microorganism isolated from the test, the growth of the species isolated was ascribed unequivocally to faults with response to the material/technique used in conducting the sterility test. A 2-year review of Nephron's change control management systems demonstrated there were no other investigations opened for sterility test failures, no invalidated out-of-specification sterility test results, and no particulates related to sterility testing. Historical review supports this is an isolated event and no systemic issues were identified. There is no potential impact to patient safety as subsequent sterility testing and other release testing specifications were met prior to product release.

As an interim control, the currently implemented sterility procedure requires an excursion report to be initiated in accordance with SOP-SC-MB-6204 for any positive sterility result. All positive results require escalation to QA management in daily escalation and review meetings.

Corrective and Preventive Actions (CAPA-0000043, *Sterility Testing Training and Related Procedure Updates*, Due Date: 10/10/2025 Attachment 59)

Nephron has committed to the following corrective and preventive actions:

1. Revisions to MTM-SC-MB-6308, *Sterility Test Procedures*, as outlined below, with a target completion date of October 3, 2025.

- Include the requirement of photographs taken against a contrast board with a negative control as a comparison in the event of an abnormal, inconclusive, or turbid sample is found.
- Define a subculture process for suspected turbid canisters.
- Clarify results which are to be classified as inconclusive with a defined process for canisters with suspected non-viable particulate. Outline and further define the process of evaluating an abnormal result, which includes leaving the canisters in incubation for the full 14 days.
- Prior to initial incubation, require personnel to evaluate the test samples against the negative control for any abnormalities.
- Update FRM-SC-MB-1661-R, *Certification-Sterility Test Procedures (14-Day Sterility Test)* to make the training process more robust for evaluating liquid media as part of sterility testing evaluations.

2. Revisions to SOP-SC-MB-6204, *Microbiological Excusions and Investigations,* as outlined below with a target completion date of October 6, 2025.
   - Define an escalation process in the event of a sterility failure, including but not limited to, the immediate initiation of a laboratory investigation and manufacturing investigation simultaneously.
   - Outline required steps for proper laboratory investigation actions for a sterility test result, including steps to identify a particle if the abnormality is non-microbial in nature.
   - Revisions to SOP-SC-QA-1220, *Deviations and Investigations* – Target completion date: 10/06/2025 Define if an excursion report is initiated due to an abnormal product sterility test result, a manufacturing investigation will be initiated in tandem with an excursion report.

Through procedural revisions, enhanced documentation practices, and retraining of staff, Nephron will strengthen sterility testing oversight and ensure robust compliance with regulatory standards for sterility assurance and product disposition.

OBSERVATION 4.1:

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

1. Your firm's visual inspection methods used for inhalation products are inadequate. Currently, this inspection process for visible particulates, discoloration or turbidity, a critical defect, includes inspecting 50 blow fill seal (BFS) units per hour and AQL sampling at level 0.065%. Your process has not been validated to ensure your inspection method can adequately detect these defects in all products effectively across all inspectors. In 2025, you generated approximately five (5) defects generated for particles, cloudy, white specks, and dark particles.

RESPONSE 4.1:

An internal review confirmed procedures and training for inspection of visible particulates, discoloration, and turbidity are established and in place.

The observation also references "approximately five defects recorded in 2025." Of these, three were suspension products and two were inhalation solutions. Each case was captured through the Nephron quality complaint system, investigated, and resolved with CAPA where appropriate. None of these cases posed a risk warranting recall or market action. The limited number of events reflects isolated, case-specific issues already addressed through routine complaint handling and inspector training, not a systemic weakness of the visual inspection method.

Immediate Actions:

During the inspection, Nephron provided investigators with procedures (including, SOP-SC-QA-5202, *Finished Product Attribute Inspection*), complaint records, batch records and COAs (Actions 181, 212). Additional requested materials, including photographs of die-gap cleaning activities and a storyboard of particulate-related complaints with associated investigation summaries, were generated in real-time to aid in the discussion (Actions 266 and 268). Nephron staff explained the derivation of AQL sample sizes, categorization of defects, and the regulatory distinction between inhalation solutions governed by USP <5> and parenteral products governed by USP <790>. Investigators were reminded multiple times by Nephron SMEs that USP <5> does not mandate 100% unit-by-unit inspection but instead requires that particulate matter be "adequately controlled." Inspectors walked through ANSI based sampling plans, live demonstrations and supporting documentation reinforcing the controls in place for inhalation solutions.

In response, Nephron initiated CAPA-0000047 *Inspection Finding for Inspection of Inhalation Products* (Attachment 59) immediately following inspection to formally capture the FDA's concern and strengthen the inspection program. This CAPA is preventive in nature, as the review confirmed no systemic defect patterns and no impact to distributed

product. Nephron acknowledges that attribute-based visual inspection is inherently probabilistic; therefore, effectiveness must be demonstrated through controlled conditions, qualified inspectors, and data-driven verification of detection capability across products and inspectors. These principles, reflected in USP <1790>, are addressed in our CAPA commitments below.

Impact Assessment:

An evaluation was conducted on the BFS inhalation attribute inspection program. The review confirmed:

- No systemic sterility or data integrity risk; complaints were isolated and fully investigated with CAPA where appropriate.
- Low frequency of complaints over nearly a decade of monitoring; events were isolated and sporadic, with no systemic trends identified.
- Attribute inspection results are monitored throughout production in accordance with SOP-SC-QA-5202, *Finished Product Attribute Inspection* (Attachment 60) with defects documented in batch records and, when applicable, on FRM-SC-QA-5202 forms, tracked and trended under SOP-SC-QA-1104, *Responsibilities of the Quality Unit* (Attachment 61). Additional safeguards include complaint trending and QA oversight.

This assessment reflects the same explanation provided to inspectors onsite. QA's multi-tiered complaint investigation process and ongoing monitoring were clarified as the governing mechanisms for ensuring that all inspection-relevant events are detected, evaluated, and documented prior to batch disposition. The low frequency of isolated complaints supports that the program is in a state of control, with FDA's observation highlighting an opportunity for preventive enhancement rather than correction of a systemic failure. Based on this evaluation, the cited defects present no risk to product quality, sterility assurance, or patient safety.

Corrective and Preventive Actions (CAPA 0000047, *Inspection Finding for Inspection of Inhalation Products*, due 1/30/2026) (Attachment 59):

To ensure the robustness of our inspection program and eliminate any ambiguity, Nephron has initiated preventive CAPA-0000047 to drive enhancements that strengthen inspector qualification and documentation, targeted for implementation by January 30, 2026.

1. **Enhancements to Inspector Qualification Program**

   Nephron recognizes that for inhalation solutions, USP <5> requires particulate matter to be adequately controlled and does not mandate 100% inspection. The attribute inspection program has historically ensured this control, as evidenced by low complaint rates and no recalls. To further strengthen assurance, the inspector qualification program will be enhanced to incorporate expanded challenge sets (covering particulates, discoloration, turbidity, and other relevant attributes), representative workload simulations, and defined requalification triggers (e.g., annual, extended absence, process change, complaint/audit

signal). Qualification standards will be established to demonstrate consistent detection capability across inspectors while maintaining appropriate controls on false rejects.

Principles described in USP <1790>, such as use of calibrated standards and probability-based assessment, may be applied, as appropriate, to ensure inspector capability is scientifically demonstrated under representative conditions.

2. **Procedure Revisions and Documentation Enhancements**
   SOP-SC-QA-5202, *Finished Product Attribute Inspection* will be revised to clarify defect classifications, expand the illustrated defect library, and codify inspection environment requirements (illumination range, backgrounds, rotation technique, dwell time). Setup verification will be logged in batch records for consistency. The procedure will also strengthen traceability by linking inspector qualification identity and date to batch/QA documentation. Complaint and inspection reject trending will be performed quarterly to ensure that challenge sets remain representative and current.

3. **Training and Demonstration of Performance**
   A focused training and qualification program will be implemented to reinforce expectations for both Operations and QA personnel. Effectiveness will be confirmed through practical proficiency checks using challenge sets, under controlled conditions, ensuring training is not only delivered but also demonstrated through measurable performance outcomes.

4. **Effectiveness Verification**
   QA will conduct an annual review of qualification data, complaint trends, and inspection results to confirm the enhanced program is functioning as intended. Should thresholds not be met, or should trending identify a gap, escalation through the CAPA system will be required.

Clarification on "Five Defects"

As noted above, the five defect cases cited in the observation correspond to individual complaint events, each investigated, documented, and closed with appropriate corrective actions. Three of these cases involved suspension products, where the presence of white specks or cloudy appearance reflects inherent suspension characteristics rather than evidence of inadequate inspection controls. These were not systemic inspection failures but isolated cases already incorporated into complaint trending and risk analysis. Complaint summaries and investigation reports are maintained in the quality system and were provided during inspection for review, and remain available upon request.

Given the probabilistic nature of visual inspection, the rare occurrence of isolated complaints is not, by itself, indicative of a systemic failure; trending and life-cycle feedback are used to drive prevention and continuous improvement, consistent with USP <1790> §1.3.

During the inspection, Nephron also provided the FDA with a written interpretation memo clarifying the regulatory basis under USP <5> for inhalation solutions (Attachment 62). This position, combined with the CAPA commitments outlined above, ensures the program remains aligned with compendial requirements and evolving expectations.

Accordingly, Nephron respectfully submits that the inspection program for inhalation products remains in a state of control, with preventive enhancements in CAPA-0000047, ensuring continued alignment with compendial and regulatory expectations, thereby sustaining patient safety and product quality.

OBSERVATION 4.2:

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

2. You do not have sound scientific justification for not performing visual inspection for identifying particulates, a critical defect in blow fill seal ophthalmic products manufactured in your facility.

RESPONSE 4.2:

An internal review confirmed that Nephron has sound scientific justification documented for performing Particulate Matter Testing as a supplemental test method for detection of particulate matter in the ophthalmic product manufactured at its facility, in compliance with USP <771>, USP <790>, and PDA Technical Report 79.

USP <771> requires 100%-unit inspection for package acceptability for ophthalmic products and directs to USP <1790> when inspection is hindered. USP <1790> explicitly defines BFS containers as examples of difficult-to-inspect products (DIPs), and reference to PDA Technical Report 79 is made for expanded examples of DIP products, including viscous solutions. For DIPs, USP <1790> requires:

- 100% inspection for package/closure defects, and
- Supplemental destructive or alternative particulate testing, since detection probability during routine 100% inspection is reduced

The only ophthalmic drug product manufactured by Nephron Pharmaceuticals is Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1%, a topical ophthalmic. This product is filter sterilized prior to filling on Production Line 26, a Rotary Blow Fill Seal (BFS) machine which uses a closed-parison process to form, fill, and seal the 0.5mL eye drop vials. All vials undergo 100% in-line leak detection via vacuum decay by a Wilco Leak Detector, an automated container closure integrity testing machine, in compliance with USP <1790> requirements for 100% inspection for package/closure defects. All vials which do not pass vacuum decay leak detection testing are rejected and segregated from accepted product.

The product is viscous, with acceptable viscosity between 15 – 35 cPs per FPS-SC-AS-3820, *Oxymetazoline HCl Ophthalmic Solution, 0.1% Finished Product Specification*. Due to viscosity and translucent BFS container, there are two (2) qualifying criteria to be considered DIP per USP <1790> and PDA Technical Report 79, further outlined below.

On June 1, 2022, USP–NF 2022 Issue 3 was published, indicating that USP <771> *Ophthalmic Products —Quality Tests* would be required to adhere to USP <790> *Visible Particulates in Injections* for 100% Visual Inspection to demonstrate that batches are essentially free of visible particulates prior to batch release. In response, Nephron initiated an Equipment/Process change control CR-05451, *Visual Inspection of Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1%* to comply with the chapter updates (Attachment 63). As part of the Engineering Action included in this change control, Process Development Study PD-22-219 was executed to perform a risk assessment to identify potential risks within manufacturing process for ophthalmic products (Attachment 64). The manufacturing process flow and associated potential failure modes are within Figure 1 of the risk assessment summary report (page 4 of PDSR-22-219). Following the execution of risk analysis, the risk evaluation concluded these were low-risk (R1), managed through established controls, and did not warrant process modifications. The risk analysis can be reviewed within Attachment 4 of PDSR-22-219 on pages 22-43.

A blinded threshold study was then conducted within PD-22-226 using potential intrinsic particle types (LDPE, Burnt LDPE, stainless steel, platinum-cured silicone, and silicone, as determined through PD-22-219) across five size bands (100–1100 µm) for a challenge set of 750 eye-drop vials labeled with UV ink to ensure blinded challenge (Attachment 89). The study results showed manual inspectors detected only 39.38% of particle defects (44.11% after excluding one outlier). Only seven of 25 material/size combinations (eight of 25 post-outlier exclusion) achieved the ≥70% probability of detection recommended by USP <1790>. This low detection rate substantiates DIP categorization in accordance with USP <1790>, in addition to the product's viscous solution with the tendency to foam, and the translucent BFS eye drop vial container closure. In summary, the visual inspection challenge confirmed the difficult to inspect nature of the product and container closure "hinders or precludes" the use of USP <790> 100% Visual Inspection methods, as documented in the supporting memorandum (Attachment 65), which provides scientific justification for the supplemental particulate matter control strategy in accordance with USP <1790>.

As a result, a supplemental method was pursued as a result of the findings of PD-22-226. Method Validation Protocol MVP-SC-CTM-6656-001 – *Method Validation of "Particulate Matter Testing of Oxymetazoline HCl 0.1% Ophthalmic Solution"* was executed to validate the use of CTM-SC-AS-6656 (CR-06268) "Particulate Matter Testing of Oxymetazoline HCl 0.1% Ophthalmic Solution" as an alternate method of visible particulate detection ≥90µm, in accordance with USP <1790> and PDA Technical Report 79 (Attachment 66). The results of MVP-SC-CTM-6656-001 were summarized in Summary Report SR-SC-CTM-6656-001, which found that the test was validated successfully with a recovery rate of 91% across all particle types tested, far surpassing the visual inspection detection rate of 44% (Attachment 67). As such, CTM-SC-AS-6556 was implemented under CR-06268, and a new specification, IPS-SC-AS-4219, *Oxymetazoline HCl Ophthalmic Solution, 0.1% WIPS In Process Product Specification* was implemented under CR-06291 to define the testing

requirements to perform Particulate Matter Testing on the product for visible particles (≥90µm), in addition to subvisible particulate matter (≥10µm, ≥25µm, and ≥50µm) testing requirements already in place for finished product (Attachment 68).

JOS-CR-06291-01, *Justification of Specifications for IPS-SC-AS-4219, Oxymetazoline HCl Ophthalmic Solution, 0.1 WIPS In Process Product Specification*, was completed to document the justification of the selection of tests and acceptance criteria included in the specification document (Attachment 69). The testing was based on USP <771> *Ophthalmic Products – Quality Tests*, and an Acceptance Quality Limit (AQL) was set per ANSI/ASQ special inspection S4 for destructive testing with limits in place for particles as a major defect (AQL 0.25). Based on the theoretical yield of 588,235 vials for the 200kg batch, a sample size of 200 vials minimum was selected per lot. As a worst-case approach, 210 vials were required to be tested (70 vials from beginning, 70 vials from middle, and 70 vials from end of lot, and are recorded in the associated batch record.

Immediate Actions:

During the inspection on August 20, 2025, during a tour of Visual Inspection operations, the investigator asked if 100% Visual Inspection was performed on the ophthalmic products produced by Nephron. Nephron Subject Matter Experts (SMEs) explained that 100% Visual Inspection was not performed on the one (1) ophthalmic product produced onsite, as the product was determined to be difficult to inspect per USP <1790> and PDA Technical Report 79. The investigator requested documented justification be provided for this product being deemed difficult to inspect, including photos of the product's container closure. The following morning, the following was provided to the investigator's Box account:

- Action 386 – Documented Justification for Not 100% Visually Inspecting Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1%, including the following documents:
  - CR-05451 Process Change Project Record Report, *Visual Inspection of Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1%* (Attachment 63)
  - Memorandum – Justification for Removal of 100% Visual Inspection of Oxymetazoline Hydrochloride Ophthalmic Solution 0.1% (Attachment 65)
  - JOS-CR-06291-01, *Justification of Specifications for IPS-SC-AS-4219, Oxymetazoline HCl Ophthalmic Solution, 0.1% WIPS In Process Product Specification* (Attachment 69)
  - FRM-SC-QA-1901-A, *Customer for Contract Manufacturing Review and Approval Form* for PDSR-22-226 (Attachment 70)

Upon investigator arrival on August 21, 2025, a filled, physical vial of Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1% was provided to the investigator. The investigator declined to hold or examine the physical vial and clarified the request to be photos of the container closure on a black and white background. After clarification of the expectation of the investigator regarding the container closure photos, the following was provided shortly after the start of inspection activities:

- Action 389 – Photos of Container Closure, including the following:
  - One (1) photo of a five (5) vial card of Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1% on the black background of a Light Booth (Attachment 71)

- One (1) photo of a five (5) vial card of Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1% on the white background of a Light Booth (Attachment 72)

Midday, on August 21, 2025, the investigator asked Nephron SMEs if the requested justification and container closure photos had been uploaded to their Box account. Nephron SMEs confirmed the requested documents had been provided and asked the investigator if they would like to discuss the documents provided. The investigator declined the opportunity to discuss the justification provided, but confirmed receipt of the requested documentation.

In the afternoon of August 21, 2025, the investigator requested the last three (3) years of customer complaints received for the ophthalmic products manufactured at Nephron. Nephron SMEs clarified that the only ophthalmic product manufactured onsite is Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1%, which is contract manufactured. Therefore, Nephron does not own the Abbreviated New Drug Application (ANDA) nor the pharmacovigilance responsibilities for the product. However, it was clarified that Nephron performs manufacturing reviews for Drug Product Quality Complaints received by the ANDA owner to support the completion of their complaint report, in accordance with the associated Quality Agreement. By the end of day on August 21, 2025, the following was provided to the investigator:

- Action 434 – Complaint Log Oxymetazoline Last 3 Years (Attachment 73)

Impact Assessment:

Conclusions are summarized below:

- Translucent 0.5 mL vial and product viscosity/foaming limited the ability to perform 100% visual inspection. See USP <771>, USP <790>, USP <1790>, and PDA Technical Report 79.
- Particulate Matter Testing demonstrated higher detection rates (overall and by particle type/size) than 100% manual visual inspection. See PDSR-22-219, PDSR-22-226, and CR-05451.
- Control Implemented: Particulate Matter Testing adopted as alternate method, aligned with ANSI/ASQ S4 sampling plan with particles classified as a major defect (AQL 0.25). See SR-SC-CTM-6656-001 and JOS-CR-06291-01.

Nephron review confirmed the current implemented approach far surpasses the accuracy of manual 100% Visual Inspection particulate matter detection capability for the drug product. Therefore, there is no impact to the identity, strength, purity, and quality of Oxymetazoline Hydrochloride Ophthalmic Solution, 0.1%.

Process Alignment Actions:

Based on Nephron's manufacturing process, as a continuous improvement effort, SOP-SC-QA-5202, *Finished Product Attribute Inspection* was updated under CR-17363 to include free-floating particulates as a visual defect in vials with a critical classification. This is attributable to the discovery of the potential for intrinsic particulate matter to be generated from the die gap following extrusion stop during rotary BFS manufacturing. As free-floating particulates were added to the procedure as a critical defect, to ensure alignment of defect

classifications for particulate matter in BFS vials, IPS-SC-AS-4219 will be updated under. This revision will tighten the specification from "Accept on 1 particle, Reject on 2 particles", to "Accept on 0 particles, Reject on 1 particle".

These actions ensure that there are adequate production and process controls in place to assure that topical ophthalmic drug products manufactured by Nephron have the identity, strength, purity, and quality that they are purported or represented to possess by ensuring the highest level of particulate identification possible through utilization of Particulate Matter Testing as an alternate test method to visual inspection, in compliance with USP <771>, USP <790>, and PDA Technical Report 79.

OBSERVATION 4.3 a b c e:

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

4.3. Your 100% visual inspection program used for inspecting injectable products is deficient for the following reasons:

a. Your 100% visual inspection program does not challenge robust, worst-case conditions for identifying defects of varying criticality for sterile liquid injectable drug products manufactured in your facility. Currently, your program qualifies your inspectors for (1) one hour whereas your shift is for 12 hours. Based on the validated batch sizes for products manufactured at your facility, inspectors are required to demonstrate competency in only a fraction of the units identified below. For example, for Sterile Water for Injection USP, inspectors are deemed qualified after evaluating a single tray containing 296 units with 34 defects at 100% competency, whereas the theoretical batch size yields 636,364 vials. This evaluation can occur up to three (3) times if failures are identified. Your visual inspection qualification does not demonstrate defect detection performance under actual production conditions.

b. You did not establish a process to ensure created test kit defects are not memorized during qualification administration. Visual inspectors who require requalification or fail qualification are retested using the same kits, allowing for potential memorization of defective units. The same kits are reused for second and third attempts, as well as for annual visual inspection testing, increasing the risk that operators become familiar with known defects.

c. Your 100% visual inspection post-test qualification challenges inspector competency on product simulated kits created by visual inspection training supervisors rather than real product. You have not demonstrated these kits along with the created defects are equivalent to products manufactured in your facility and suitable for qualifying inspectors.

e. The training of your 100% manual visual inspection trainers is inadequate in that they are deemed qualified on the test kits they create. Additionally, per your Quality Operations Sr. Manager, of the three (3) trainers, one (1) is not qualified to perform 100% visual inspection on product and the other two (2) have not performed any visual inspection on finished products manufactured at your facility in at least six (6) years. All trainers have the responsibility of confirming or invalidating defects identified by inspectors during manufacturing operations. For 2025, you generated approximately

eight (8) 503B complaints related to missing label, plastic particles, plastic in port and leaking bags.

RESPONSE 4.3 a b c e:

Nephron's 100% manual visual inspection (VI) program is established, documented, and consistently executed under SOP-SC-QA-4366, *Quality Attribute Testing - Visual Inspection* (Attachment 74), SOP-SC-QA-1606, *Visual Inspection Training and Certification* (Attachment 75), SOP-SC-QA-1201, *Fabrication and Maintenance of Visual Inspection Test Kits* (Attachment 76). Inspectors are trained, qualified, and observed prior to inspecting commercial batches. All parenteral products released for distribution undergo 100% manual VI by certified personnel, followed by AQL inspection, with trigger for immediate investigation if pre-defined defect-rate thresholds at the 100% stage are exceeded or if AQL sampling inspection fails. This layered approach is consistent with FDA guidance and ensures robust control.

The observation notes that inspectors shall demonstrate competency "based on the validated batch size." As discussed during the inspection, industry and USP <1790> standards recognize representative worst-case challenge sets (including fatigue-managed modules and defect types), not full batch-size or shift duration, as the basis for qualification. Fabricated surrogates supplement naturally occurring defects and are designed to mimic true product characteristics, consistent with USP <1790>. Our enhancements formalize this approach. Additionally, Nephron had provided an updated version of the chart included in observation 4.3.a which reflected sub-lot batch sizes. During the close-out meeting the inspectors agreed to update the chart but this revision was not made in the Form FDA 483 Amendment 1.

The program has consistently ensured that parenteral units receive 100% manual VI prior to AQL sampling. A preventive CAPA has been opened to formalize and complete the following enhancements, ensuring the program remains in a state of control and aligned with evolving expectations:
(i) robustness of qualification exercises under representative worst-case conditions,
(ii) lifecycle controls on test kits to eliminate any potential for memorization, and
(iii) trainer qualification and ongoing practice.

Immediate Actions:
During the inspection, Nephron provided the investigators with SOP-SC-QA-1606, *Visual Inspection Training and Certification* (Attachment 75), the associated training curricula, and the current defect library. Training and qualification records for active inspectors were also provided, confirming that all inspectors had documented competency testing and certification prior to performing production inspections. At the FDA's request, defect kits were presented, and the creation and maintenance process under SOP-SC-QA-1201, *Fabrication and Maintenance of Visual Inspection Test Kits* (Attachment 76), was explained, including the use of both actual rejected units and fabricated surrogates where naturally occurring defects are

infrequent. The only defect kits reviewed during the inspection were for prefilled syringes, which is not a container closure system currently used for any product manufactured at the facility as was explained to the investigators.

Nephron further clarified that inspectors must achieve 100% accuracy in kit-based defect recognition before qualifying for production duties, with results documented and attempts limited under controlled conditions. It was emphasized that 100% manual VI precedes AQL inspection and that pre-defined defect-rate thresholds at the 100% stage trigger immediate investigation in addition to AQL thresholds, ensuring a layered system of safeguards.

To address FDA's concern regarding inspector fatigue, Nephron presented SOP-SC-QA-4366 *Quality Attribute Testing - Visual Inspection*, which requires operators take a documented 5-minute break away from light each hour, supported by rotations to sustain performance across extended shifts. In addition, operators are required to take a 30-minute meal break during the shift, with flexibility to take additional breaks as needed. . This approach aligns with USP <1790> which states:

> "On the basis of industry experience, it is recommended that inspectors be given a documented break from performing inspection at least every hour. This break should allow time to rest the eyes and mind and may be achieved with a short rest (e.g., 5 min) or a longer meal break. This need for regular breaks may also be met through rotation to a non-inspection function, such as material handling or documentation."

Training materials and break logs were also presented, demonstrating compliance to procedure and rotations throughout other activities within the duration of the shift.

As an immediate action and interim control measure, Nephron required a qualified trainer or QA supervisor to observe each inspection station per shift until the trainer requalification program is complete.

Finally, supervisory oversight was demonstrated through FRM-SC-QA-4366-I, *Visual Inspection Technique Observation Checklist*, which QA uses to verify proper technique during production and to ensure immediate correction of any deviation.

Impact Assessment

An evaluation of the 100% manual visual inspection (VI) program for sterile injectables confirmed that:

- All products undergo 100% VI prior to release. AQL provides a second safeguard. Both 100% visual inspection results and AQL results are trended and reviewed by the Quality unit.
- 2025 complaints were investigated and determined to be isolated, assignable to handling/supplier causes, etc., with no systemic trends or linkage to inspector qualification.

- Inspectors require 100% kit accuracy; defect-rate thresholds trigger investigation; AQL and complaint trending confirm layered detection. Visual inspection is inherently probabilistic per USP <1790>, and Nephron mitigates this through qualified inspectors, scientifically justified challenge sets, fatigue management, and QA oversight.

The injectable VI program remains in a state of control; FDA's comments reflect opportunities for preventive enhancement, not evidence of systemic failure.

Corrective and Preventive Actions (CAPA-0000048 due January 30, 2026):
To address items a, b, c, and e noted in observation 4.3, a preventive CAPA 0000048 has been initiated to strengthen the visual inspection program, targeted for implementation by 01/30/2026.

1. **Procedure Revisions and Documentation Enhancements**
   Nephron is revising its governing procedures to ensure inspector qualification reflects representative worst-case conditions. SOP-SC-QA-1606, *Visual Inspection Training and Certification* (Attachment 75), is being updated to expand qualification exercises beyond the current hourly modules, incorporating start- and end-of-shift simulations, throughput challenges, and a broader range of defect types. These changes will demonstrate inspector competency under conditions that more closely approximate extended operations and will explicitly tie fatigue-mitigation requirements from USP <1790> to qualification design.

   In addition, SOP-SC-QA-1201, *Fabrication and Maintenance of Visual Inspection Test Kits* (Attachment 76), is being revised to reinforce kit lifecycle management. While retirement and replacement practices already exist, the updated procedure will require documented kit randomization, the creation of additional kits for each container type to prevent reuse, and blinding of all units with QR-only identifiers. Custody logs will be implemented to track kit use and ensure integrity of the certification process. Finally, associated batch and QA documentation will be reinforced so that inspector identity, qualification date, kit identification, and supervisory oversight records are directly linked to production campaigns, improving traceability and providing clear evidence of compliance.

2. **Training and Awareness**
   All inspectors, trainers, and QA supervisors will be retrained on the revised procedures, with particular emphasis on qualification under worst-case conditions, proper use and rotation of randomized kits, and escalation triggers at both the 100% VI and AQL stages. The refresher training course will also incorporate complaint learnings and defect-rate trending to ensure continuous reinforcement of expectations and feedback loops from quality data.

3. **Defect Library Expansion and Validation**

Nephron's defect library already encompasses critical, major, and minor defect classes and is actively maintained under SOP-SC-QA-1201, *Fabrication and Maintenance of Visual Inspection Test Kits*. To further strengthen robustness and ensure alignment with USP <1790>, the library is being expanded incrementally to cover additional edge cases such as low-contrast particulates, small-size defects, and borderline appearance attributes. Each category will be supported by photographic standards and detailed descriptors to reinforce consistency across inspectors.

Fabricated defects, which are used when naturally occurring examples are infrequent, will continue to supplement the library but will now be formally demonstrated as equivalent to true rejects through scientifically justified methods such as spiking or microscopy. Acceptance criteria will be defined in line with USP <1790> probability-of-detection principles. The library will also undergo a structured quarterly refresh cycle, with degraded units retired and replaced, ensuring that all challenge sets remain representative, reliable, and scientifically robust.

4. **Qualification of Trainers**
   Nephron is updating trainer responsibilities and requalification requirements to ensure those overseeing inspector performance maintain current competency and relevant hands-on practice. Trainer job descriptions will distinguish between kit fabrication and inspector training duties, ensuring clear accountability. Trainers will now be required to complete annual requalification using blinded challenge sets and to participate periodically in inspection of commercial product to maintain alignment with real-world conditions. QA will maintain a trainer qualification matrix and conduct periodic oversight reviews to ensure only fully qualified trainers are authorized to administer inspector certification.

5. **Effectiveness Verification**
   Effectiveness of these enhancements will be confirmed by requiring inspectors to demonstrate ≥90% detection of seeded defects with ≤5% false rejects. These benchmarks are consistent with published probability-of-detection expectations and provide objective measures of program effectiveness. On-floor observations and trending of AQL and complaint data will be used to verify sustained performance, with results reviewed during Management Review to ensure visibility and continuous improvement.

Accordingly, Nephron respectfully submits that the inspection program for parenteral products remains in a state of control, with preventive enhancements in CAPA-0000048, ensuring continued alignment with compendial and regulatory expectations, thereby sustaining patient safety and product quality.

OBSERVATION 4.3 d:

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

4.3. Your 100% visual inspection program used for inspecting injectable products is deficient for the following reasons:

d. You have not qualified the inspection procedure used to measure overfill volumes for sterile prefilled syringes for your 100% manual visual inspection processes for 503B operations. Currently, you use the graduations on retrofitted syringes to create sleeves which are used as measuring devices. These sleeves are intended to measure volume that exceeds the graduations applied the product's container closure system. These devices are uncontrolled and lack standardization.

RESPONSE 4.3 d:

An internal review confirmed Nephron previously used graduation extension sleeves during 100% manual visual inspection of prefilled syringes where target fill volumes extended beyond the last printed graduation. Prefilled syringes are not a container-closure currently used for any product manufactured at this facility. This practice was intended strictly as a visual reference aid within the inspection process, not as a formal batch release test or quantitative fill-volume determination. All syringe release decisions relied on established in-process controls and quality testing. At the time of the audit, no syringe products within expiry were distributed on the market. All of the above were explained to the inspectors during the inspection itself.

Nephron recognizes FDA expectation even reference tools used within visual inspection must be controlled, standardized, and scientifically justified.

Immediate Actions:

At the time of inspection, Nephron provided FDA investigators with SOP-SC-QA-4366, *Quality Attribute Testing - Visual Inspection* (Attachment 74) and explained the purpose and use of the extension sleeve as a visual aid. Investigators were informed the sleeve was not a release method.

Nephron confirmed to investigators no syringe products within expiry are on the market and committed syringe production will not resume until methods described below are fully implemented and qualified.

As part of the relaunch of this container-closure system, Nephron will replace the use of retrofitted syringe sleeves with controlled comparator syringes, gravimetrically verified at the target fill volumes, logged, and periodically replaced. The comparator syringes will serve as a standardized reference for inspectors during 100% visual inspection.

OBSERVATION 5:

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particles air filters under positive pressure.

Specifically, your firm failed to follow procedures to ensure alarms impacting classified areas are promptly responded to, investigated, and corrected.

For example, during a walkthrough of the facility on 11 Aug 2025, we observed that the alarm for the Blow Fill Seal (BFS) "man" pass-through had been alarming for a significant amount of time. The Material Transfer Operator (SL) present reported, "I don't do anything about alarms." The Corporate Chief Quality Officer confirmed the alarm had been active since the morning. She further reported that operators are trained to report and escalate alarms to management; however:

a. ***No operator reported or escalated the alarm***
b. ***No management oversight or monitoring of the alarm condition was evident.***
c. ***No assessment was made regarding the potential impact of the alarm.***
d. ***No investigation was initiated until we inquired.***

Firm management later confirmed that the alarm indicated a differential pressure failure signifying loss of positive pressure from the ISO 7 area, which is the background area for BFS operations, and had a controlled not classified (CNC) area.

Your firm failed to ensure that alarms critical to maintaining aseptic conditions were promptly addressed, escalated, and investigated. These deficiencies in alarm management and oversight create an unacceptable risk of microbial ingress and contamination of sterile products. The lack of effective alarm response undermines sterility assurance and patient safety.

RESPONSE 5:

During the inspection on 08/11/2025, FDA inspectors interviewed material transfer operator SD regarding a stack light was alarming on the first floor in Clean Not Classified (CNC) Room 133 in front the ISO-8 cleanrooms (Handwashing Room 137, Material Transfer Room 139, Personnel Exit Vestibule Room 141B) (Attachment 77), to which operator SD appeared not to respond. Operators are trained to respond to stack light alarms, and if their response does not resolve the alarm, then the operator is to escalate the alarm to their next level of management. TopView is a comprehensive alarm notification and alarm management software used to report and monitor alarms on the cleanrooms. Alarms in TopView were generated for the cleanroom differential pressure from ISO-8 Pre-gowning area Room 137 to Clean Not Classified Room 133 and from ISO-8 Exit Vestibule Room 141B to Clean Not Classified Room 133, and these TopView alarms were appropriately evaluated and addressed per requirements in SOP-SC-QA-1216 *TopView Alert Notification System* (Attachment 78) and SOP-SC-QA-1217 *Alarm Annotation System* (Attachment 79). The stack light alarms the investigators observed were alert (not action) limit alarms; there was no differential pressure failure in the affected areas.

On 08/11/2025, Nephron immediately began an investigation into the lack of stack alarm response, without prompting from investigators or requiring follow up queries to open the event deviation. As part of the deviation investigation, the operator was interviewed and an internal review of the procedures and processes associated with stack light response and escalation was conducted.

5.A - Immediate Actions:
Review of employee training records confirmed the employee was trained on stack light response. During interviews with the employee, they confirmed they recall being trained on the procedures relating to stack light response and escalation. Additionally, interviews of other personnel in the area on August, 11, 2025 08/11/2025 while the stack light was alarming were performed to gain a better understanding of employee comprehension regarding this process. These interviews confirmed a more robust reporting mechanism is required with clear responsibilities outlined for stack light response and escalation. A summary of the interviews is included as part of DEV-0000062 *Inspection Finding – Employee(s) did not Escalate Stack Light Alarms.*

Alarm Process Overview and Investigative Findings of DEV-0000062:

1. The alarm system is not designed to differentiate alarm severity – both visual and audible indicators are the same whether the parameter is an:
    - Alert limit alarms: assessment of alarm required but action may not be needed
    - Action limit alarms: assessment and action are required

2. The stack light alarms are triggered by various factors. Expected alarms are self-resolving (e.g., resolution of alarm upon closing of material transfer doors) and unexpected alarms (e.g., prolonged alarms in which all doors are closed and air returns are not blocked), leading to:
    - Desensitization
    - Assumptions others are addressing the alarms

3. Current alarm configuration programming is limited, making it challenging to distinguish between different threshold levels (alert vs. action conditions) based on how they are visually displayed or sound.

A decision-tree workflow will be added to SOP-SC-QA-2530, *Cleanroom Operation and Inspection* (Attachment 80) to provide operator instruction for the differentiation in expectations for operator response to alert activation vs. action activation.

5b, 5c, 5d. - Immediate Actions:
The TopView Alert Notification System is in place to identify and escalate all alarms related to temperature, humidity, and differential pressure, regardless of whether an operator has responded in the moment. Per SOP-SC-QA-1216 *TopView Alert Notification System* (Attachment 78), an alarm is generated when an associated process condition is outside the alarm parameters for longer than a defined alarm delay. In accordance with the established process, TopView alarms were generated for cleanroom differential pressure, which exceeded the defined alarm delay of <0.035 w.c. for ≥ 360 seconds with a deadband of 0.01 w.c. from ISO 8 Pre-gowning Room 137 to Clean Not Classified Room 133 and ISO 8 Exit Vestibule Room 141B to Clean Not Classified Room 133. These alarms were appropriately annotated and reviewed per procedures SOP-SC-QA-1216 *TopView Alert Notification System* and SOP-SC-QA-1217, *Alarm Annotation System*. Review of Plant Information (PI)

Historian data confirmed positive pressure was maintained between the classified and clean not classified environments.

As per SOP-SC-QA-1217 *Alarm Annotation System*, all alarms generated by the system are acknowledged and annotated by the end of the following business day after the alarm has ended. Quality personnel verify and sign-off on all annotations and, if required, identify any further action needs to occur such as quality investigation per SOP-SC-QA-1220, *Deviations and Investigations*. Per section 6.6.4 of SOP-SC-QA-1217, all alarms shall be Quality Closed within seven (7) business days from the date the alarm was first annotated. If the alarm cannot be closed due to the need for further investigation, escalate the alarm to a Quality Event (Deviation) per SOP-SC-QA-1220, *Deviations and Investigations*.

All alarms for ISO-8 Pre-gowning Room 137 and ISO-8 Exit Vestibule Room 141B for the stack light in Clean Not Classified Room 133 observed by FDA inspectors on 08/11/2025 were annotated by Utilities/Facilities personnel per procedure. Review of Plant Information (PI) Historian data of the differential pressure in ISO-8 Pre-gowning area (Room 137) and ISO-8 Exit Vestibule (Room 141B) to Clean Not Classified (CNC) Room 133 on 08/11/2025 confirmed positive pressure was maintained between the classified and Clean Not Classified (CNC) environments throughout the duration of the alarms. All alarms for ISO-8 Pre-gowning area Room 137 and ISO-8 Exit Vestibule Room 141B for the stack light in Clean Not Classified Room 133 observed by FDA inspectors on 08/11/2025 were reviewed and closed the following business day on 08/12/2025 by Quality personnel. The classified rooms adjacent to Clean Not Classified Room 133 include ISO-8 Handwashing Room 137, ISO-8 Material Transfer Room 139, and Personnel Exit Vestibule Room 141B, all of which are not considered to be ISO-7 background rooms for the Blow/Fill/Seal (BFS) production area.

The current alert notification system detects and identifies alarms related to temperature, humidity, and differential pressure. Procedures were followed during the investigation, and assessment of the alarms was conducted as per procedure. However, a decision-tree workflow will be added to SOP-SC-QA-2530, *Cleanroom Operation and Inspection* (Attachment 80) to provide operator instruction for the differentiation in expectations for operator response to alert activation vs. action activation.

Risk Based Impact Assessment

A risk assessment was conducted for each of the observations surrounding cleanroom operations and environmental control, which included Observation #5. Following evaluation, the hazard presented by Observation # 5 was determined to be low risk to product quality due to strength of existing controls. Data review from existing detectability controls confirmed the system is currently operating in control with no impact to product on the market.

There is no impact to patient or the safety, identity, strength, purity, or quality of any production batch or lot from this event as:

- An investigation was opened on the same day, 08/11/2025, of the employee interview which identified inappropriate escalation.

- All TopView alarms were annotated by Utilities/Facilities personnel in accordance with procedure.
- These alarms were closed by Quality personnel within the 7-business day time frame.
- A root cause of the alarms was identified, documented, and corrected.
- Positive pressure was maintained between the classified environment and clean not classified environment.

Corrective and Preventive Actions (CAPA #: 1033175, *Modification to Operator Response Workflow for Stack Lights and Magnehelic Gauges*, due October 28, 2025) (Attachment 81):

The following corrective/preventive actions were determined to be necessary:

- To address the observation of lack of escalation of stack light alarm by employee SD and prevent recurrence of personnel on the production floor not escalating stack light alarms, a corrective action of On-the-Job training was completed promptly with Sterile Room personnel, including employee SD. The retraining for employee SD was completed on 08/11/2025.
- Actions outlined in Corrective and Preventive Action (CAPA) plan Project Record (PR) #: 1033175 *(CA) - Modification to Operator Response Workflow for Stack Lights and Magnehelic Gauges* will address the investigative findings of DEV-0000062 *Inspection Finding – Employee(s) did not escalate Stack Light Alarms* in which "Method" and "Machine" were determined as root causes. Method was determined to be a root cause of the lack of escalation of stack light alarms by personnel on the production floor due to the need for instructions regarding communication and documentation of stack light alarm acknowledgement. Machine was determined to be a root cause due to the current stack light configuration. Preventive actions include:
    - Stack lights will be updated to assist in operator differentiation between an alarm for alert conditions and action conditions by activating as a visual-only cue for alert, and visual + audible cue for action.
    - A decision-tree workflow will be added to SOP-SC-QA-2530 *Cleanroom Operation and Inspection* (Attachment 80) to provide operator instruction for the differentiation in expectations for operator response to alert activation vs. action activation.
    - New workflow instruction will revise current actions for usage of magnehelic gauges to ensure workflow is easy for operator usage.
    - Training on these CAPA items will be completed with applicable personnel.
- CAPA PR #: 1033175 *(CA) - Modification to Operator Response Workflow for Stack Lights and Magnehelic Gauges* (Attachment 81) will track these actions to completion, with an implementation date of October 28, 2025. Effectiveness of these actions will be verified following CAPA closure to confirm sustained compliance.

Redundant systems are in place for TopView alarm identification and assessment as per SOP-SC-QA-1216 *TopView Alert Notification System*, (Attachment 78) SOP-SC-QA-1217 *Alarm Annotation System*, (Attachment 79) and SOP-SC-QA-2530, *Cleanroom Operation and Inspection*. (Attachment 80) Any alarm in which a root cause cannot be identified is escalated in accordance with SOP-SC-QA-1220, *Deviations and Investigations*. These

procedures ensure the alarms are monitored, annotated, and assessed for potential impact and properly investigated prior to closure.

OBSERVATION 6 A:

The responsibilities and procedures applicable to the quality control unit are not fully followed. Sterile Drug Manufacturing & 503B Outsourcing Facility NPC & 503B Operations SM 08/22/2025

Specifically,

A. There is a failure of the Quality Unit (QU) to review and approve pre integrity filter testing that results in "abort" and "error." Pre-filter integrity outcomes resulting in abort or error are documented and maintained in the Pall Flowstar Integrity Tester and reviewed within the audit trails by Production management daily and quarterly. These records are not reviewed by the QU or evaluated prior to batch disposition.

RESPONSE 6A:

An internal review (DEV-0000119 *Inspection Finding – Filter Integrity results is performed quarterly*, opened 08/25/25) confirmed filter integrity tests producing numeric outcomes were properly attached to batch records and reviewed by the Quality Unit (QU). Upon completion of filter integrity testing, the results are reviewed by Production personnel and attached to the batch record and are subsequently reviewed by the Quality Unit on the manufacturing floor. Disposition occurs only after the Quality Batch Record Review department verifies filter integrity test results are passing per the validated acceptance criteria and are properly attached to the batch record per WRK-SC-BR-1250-A, *Work Instructions for the Review of Batch Record* (Attachment 82). However, intermittent attempts to analyze filter integrity resulting in "Error" or "Abort" were excluded from QU review per SOP-SC-FM-4111 *Management of Filters* (Attachment 83) These events were only reviewed and documented by Production personnel. These exclusions did not impact the overall sterility assurance of released batches, as all filter integrity tests producing a quantitative value were appropriately reviewed and approved by the QU. were appropriately reviewed and approved by the QU.

Immediate Actions:

During the inspection on 08/22/25, FDA noted the absence of QU review of "Error" and "Abort" test attempts. In response, Nephron initiated DEV-0000119 *Inspection Finding – Filter Integrity results is performed quarterly*, on 08/25/25 to investigate the observation and evaluate procedural alignment. All filter integrity test attempts, including those flagged as "Error" or "Abort," were confirmed to be retained in the Palltronic Flowstar V system audit trail, and a retrospective review was completed to confirm no impact to product quality. The vast majority of tests produced a numeric value, which could be compared to the acceptance criteria resulting in a passing value. Any failure presented would proceed through the Failure Analysis Tree outline in SOP-SC-FM-4111 *Management of Filters* (Attachment 83). Any Error message did not report a value, would proceed through the troubleshooting guidance outlined within SOP-FM-4111 *Management of Filters*. Any abort was annotated by Production personnel as required by the SOP-FM-4111 *Management of Filters*.

Inspectors were informed filter integrity tests report a numeric result are consistently compared against validated acceptance criteria. Numeric values will be reported with either a "Pass" or

"Fail" statement. These results are then attached to the record for review by Quality. All released lots are supported by successful, valid integrity results and no product may be released without passing integrity confirmation reviewed by the QU. However; tests report "Error" or "Abort" do not report a numeric value. At the time of the inspection, "Error" or "Abort" were not track and trended. As a result of a retrospective review demonstrates all errors, aborts, and failures were properly addressed with either effective troubleshooting or escalation, via a deviation, in accordance with SOP-SC-FM-4111 *Management of Filters*.

Impact Assessment:

All processes requiring sterilization by filtration depend on the use of validated, integrity-tested filters to ensure product sterility. Filters used in aseptic processing must demonstrate integrity in accordance with the validated filter integrity testing program. Test results must meet established acceptance criteria to confirm the filter remained integral throughout the process and it performed as designed.

Sterility testing of the finished commercial product provides additional assurance that filters were integral and effective in preventing microbial contamination. Aseptic process simulations (media fills) routinely qualify the overall aseptic process, including operator performance, equipment setup, and environmental controls. The impact of any deviation or change involving filter integrity must be assessed with respect to product sterility, regulatory compliance, and the validated state of the process.

Corrective and Preventive Actions (CAPA-6A, due October 15, 2025):

To address this observation and prevent recurrence, CAPA-6A includes:

- SOP-SC-FM-4111 *Management of Filters* (Attachment 83) will be updated to require all results, including the nonnumeric data reported from Errors are Abort will be attached and reported with each batch record.
- SOP-SC-FM-4111 will be updated to ensure "Errors" and "Aborts" are attached to the record and give direction these results to be considered testing attempts subject to the Analysis Decision tree.
- SOP-SC-FM-4111, and all applicable forms and work instructions, will be updated to ensure QU reviews all outcomes ("Pass," "Fail," "Error," and "Abort") of testing at the batch level, on the manufacturing floor, prior to submission of the record to Quality Batch Record Review. This will ensure all applicable testing is attached, including "Errors" and "Aborts" for final review and dispositioning.
- Trending of "Error" and "Abort" will be evaluated during historical review of deviation escalation.

SOP-SC-FM-4111 is undergoing revision to require all test attempts, including "Error" and "Abort," be treated as official results, attached to the batch record, and reviewed by QU before to disposition.

All corresponding forms are being updated to ensure all testing attempts are documented and reviewed. A "QA Reviewed By" signature field is being added. Updates include:

- WRK-SC-FM-4111-C *Filter Integrity Testing for Rommelag 460 BFS Machines*
- FRM-SC-FM-4111-B *Offline Filter Integrity Test – Cartridge Filters*
- FRM-SC-FM-4111-E *Oxymetazoline Offline Filter Integrity Test Certification*
- FRM-SC-FM-4111-J *Offline Filter Integrity Test – Capsule Filters*
- FRM-SC-FM-4111-G *Outsourcing Offline Filter Integrity Test – Forward Flow*

Additionally, FRM-SC-PR-4322-B *End of Lot Checklist* is being updated to include verification all test results from FIT analyses are attached to the batch record. A QA review step will ensure the QU has direct oversight of all filter-related test outcomes and associated production lots. This will include review of the audit trail from the filter testing unit.

Training / Awareness:

Operations staff and relevant QU personnel will be trained on revised procedures, emphasizing the importance of complete record review, including "Error" and "Abort" outcomes. Training will reinforce responsibilities under the updated process and industry best practices for data integrity and sterility assurance. Effectiveness will be measured through knowledge checks and direct observation during routine batch record review

Effectiveness Verification:

To verify the effectiveness of this CAPA, the QU will perform a review of a minimum of 30 consecutive filter integrity test records, including any aborts or errors, within 60 days of CAPA closure to ensure QU review has been completed per revised process and procedures. The EV will confirm all production and QU manufacturing personnel, performing or reviewing filter integrity tests, have completed training with a successful knowledge assessment documented.

OBSERVATION 6 B:

The responsibilities and procedures applicable to the quality control unit are not fully followed.

B. Your Quality Unit failed to adequately exercise its authority and responsibilities, including but not limited to, implementing effective procedures, and conducting adequate oversight to support the safety, effectiveness, and quality of the sterile drug products you manufacture. For example, but not limited to:

a. Your firm failed to exercise appropriate controls over computer or related systems to assure that only authorized personnel institute changes in master production and control records, or other records by maintaining oversight of BFS HMI Data, Backups, and Error Logs. For example, but not limited to, during the walkthrough of the facility on 12 Aug 2025, we observed the following:

1. Your Chief Technology Officer presented a file named "Exception.txt", which contained approximately 18,022 logged "Access Violation" errors from 04/17/2024–03/08/2025. Management acknowledged they were unaware of this error log. Vendor representatives were unable to explain the root cause or impact of the recurring access violations.

2. A file named "460133.err" contained additional error messages, described as the raw data file for the Error Manager Viewer Machine Event Log. The "Exception.txt" log was reported to be ancillary to this error log.

RESPONSE 6.B.a.1 & 6.B.a.2:
During the inspection, Nephron engaged the Blow-Fill-Seal (BFS) vendor, Rommelag, who was able to explain that the that *Except.txt* and *460133.err* Error Manager Files are system artifacts which, if necessary, may be used for diagnostic purposes by the vendor. This documentation was provided to the inspectors during the inspection, but they did not review. The Error Manager files referenced in this observation support back-end software functionality, as part of the validated software configuration and are not master production and control records, or other records related to the manufacture, processing, packing, and holding of a drug product.

460133.err is the encrypted raw data file that generates the *Error Manager Log*, while *Except.txt* is a vendor diagnostic artifact. The *Error Manager Log* is the quality-relevant record reviewed by QA in accordance with SOP-SC-PR-4399, *Audit Trail Review BFS* (Attachment 84) and SOP-SC-BR-1250, *Finished Product Batch Review and Release (e.g. door open, valve fault, or machine jam)* (Attachment 85). Because these background files are not related to master production and control records, they are not subject to direct QA review. These "Access Violation" exceptions occur when the program automatically attempts to access a part of the computer's memory that does not contain data and do not indicate that an individual user is attempting to access data to which they do not have access rights. While the observation described approximately 18,022 "Access Violation" errors, a review confirmed over 99 percent of these occurred during a single scheduled maintenance window, when the line was not in a validated state, and no product was manufactured. The existence of these files is not indicative of any data loss or manipulation.

The observation also referenced BFS HMI backups. An internal review confirmed that the Enterprise Backup System (Veeam) is a validated, Quality-approved solution governed under SOP-SC-IT-9301, *Electronic Data Backup*, (Attachment 86) The system incorporates multiple safeguards to ensure completeness and integrity of all audit trail backup data. While the observation described this as a lack of QU oversight, Nephron's review confirmed that completeness and accuracy are assured through validation, checksum-based integrity checks, and automated reporting, with escalation to QA via deviation procedures when required. These controls are active, documented, and subject to direct QU authority.

This observation provided further opportunity to clarify the data structure of BFS system files, and ensure that the distinction between background machine artifacts, quality-relevant audit trails, and validated backup safeguards is explicitly documented and well understood by all stakeholders.

Immediate Actions:
During the inspection on August 12, 2025, Nephron demonstrated the validated Enterprise Backup Repository for BFS machines. As part of this review, inspectors randomly selected two system files from the Error Manager Viewer (*460133.err* and *Except.txt*) for secondary examination under the assumption that they might contain quality-relevant data. Because these

files are diagnostic artifacts rather than quality records, they were not immediately identifiable to QA, or to Nephron's technical SMEs as this software was not developed internally. Nephron engaged Rommelag during the inspection to explain the purpose of these files, which required escalation to Rommelag headquarters in Germany. Following this outreach, Rommelag provided written confirmation clarifying that the files were diagnostic in nature and directly related to the Error Manager Log. Although Nephron offered this clarification, auditors did not review it during the inspection.

At the inspectors' request, printouts of *Except.txt were* generated and reviewed onsite (Actions 155 and 158). The *Except.txt* file was 54,069 lines in length, representing 18,026 unique messages. Inspectors specifically questioned whether these files represented "54,000 events that QA did not know about." Nephron clarified that 17,920 of the 18,026 entries (99.41 percent) occurred on February 12, 2023, during a scheduled maintenance window when the production line had been removed from validated state and not returned until February 24, 2023. No product was manufactured during this time. The remaining 106 entries were isolated, events appearing sporadically between February 2023 and August 2025, each representing only 0.01 percent of the total.

Rommelag confirmed the messages in *Except.txt* are diagnostic exceptions caused by network latency. These events are rare, automatically retried, and do not affect system integrity, operation, or compliance. If the warnings were not caught, the program would stop (this stop would be captured in the Audit Trail and subsequently reviewed by QA). All noted messages or events are captured in the Error Manager Log, which undergoes a multi-layered thorough review by both Operations and QA in accordance with SOP-SC-PR-4399, *Audit Trail Review BFS* and SOP-SC-BR-1250, *Finished Product Batch Review and Release*.

In parallel, Nephron presented the validated Enterprise Backup System (Veeam) to the inspection team (Actions 159 and 489). In alignment with SOP-SC-IT-9301, *Electronic Data Backup* the Veeam backup solution, validated under Performance Qualification PQ-607, (Attachment 92) incorporates multiple safeguards to ensure both completeness and integrity of backup data. Completeness is assured through validation of all targeted data blocks during backup, verification of backup chain consistency, and comprehensive automated reporting to confirm that no files are omitted or bypassed. Accuracy is maintained through checksum-based integrity checks performed during both data transfer and storage, thereby preserving data fidelity. This process is formally defined and governed under SOP-SC-IT-9301, *Electronic Data Backup* (Attachment 86). Any unresolved backup issue would be managed as a Quality Event Deviation in accordance with SOP-SC-QA-1220, *Deviations and Investigations*, ensuring that such events are identified, escalated, documented, and assessed under direct Quality Unit oversight.

Nephron provided inspectors with Rommelag's written response, process flow diagrams, and supporting documentation during the inspection. Nephron also offered multiple opportunities to review the *Error Manager Log* in conjunction with the associated batch records; however, inspectors declined to review this documentation during the inspection.

Impact Assessment

An assessment of the exception messages and associated backup process confirmed:

- No sterility assurance or data integrity impact,
- Over 99 percent occurred during a single maintenance event; remaining entries were isolated and sporadic,
- All events captured in the Error Manager Log, which undergoes multiple levels of QA review under SOP-SC-PR-4399, *Audit Trail Review BFS* and SOP-SC-BR-1250, *Finished Product Batch Review and Release* and backed by validated Veeam safeguards with checksum integrity checks and automated escalation under SOP-SC-QA-1220, *Deviations and Investigations*.

This assessment reflects the same explanation provided to inspectors onsite, where QA's multi-tiered review of the *Error Manager Log* and oversight of validated backup safeguards was clarified as the governing mechanism for ensuring all system events relevant to product quality are detected, evaluated, and documented prior to batch disposition. Based on this evaluation, these exceptions present no risk to product quality, sterility assurance, or patient safety.

Corrective and Preventive Actions (CAPA-0000050 due November 12, 2025):
To address this observation and prevent recurrence of inspection misinterpretation, a preventive CAPA (CAPA-0000050, Attachment 87) has been initiated, targeted for implementation by November 12, 2025.

1. **Procedure Revisions and Documentation Enhancements**
SOP-SC-PR-4399, *Audit Trail Review BFS* is being revised to more clearly specify that quality-relevant documentation is limited to the *Audit Trail* and *Error Manager Log*. Other system-level diagnostic files, including, but not limited to, *Except.txt*, *460133.err*, and similar machine generated files, are not intended nor subject to direct QA review, as they are part of the validated system configuration and are not used in product disposition.

SOP-SC-IT-9301, *Electronic Data Backup* is being updated to explicitly describe QU oversight of backup completeness and integrity checks. The revision incorporates a data flow diagram that demonstrates how all quality-relevant backup data are validated, verified, and reviewed under QU authority. Cross-references to SOP-SC-QA-1220, *Deviations and Investigations* will clarify escalation pathways, ensuring that any backup irregularities.

A supporting reference (Attachment 88) has been prepared for inspection-readiness, documenting the BFS system architecture and Rommelag written confirmation diagnostic artifacts do not constitute quality records. This attachment is for inspection readiness only and is not part of the controlled SOP.

2. **Training / Awareness**
QA, Operations, and IT personnel have been briefed on the revised procedure and supporting architecture reference. Training emphasized QA's role, the boundary between quality-relevant records and diagnostic artifacts, and escalation of anomalies identified in the Error Manager Log. This ensures consistent and accurate explanation during future inspections.

The Quality Unit is fully embedded in the oversight of this process, with structured multi-layered review of all BFS quality-related data, including audit trails, Error Manager Logs, validated

backups, and supporting batch documentation—prior to batch release. This governance framework ensures that data integrity is rigorously maintained, and only compliant product is released to the market.

12B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Xttrium Laboratories, Inc.

Physical Address: 3400 West Lake Avenue

City: Glenview State: IL Zip: 60026

Mailing Address (if different from physical address): c/o State License Servicing, Inc., 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: www.xttrium.com

Name of Designated Representative (DR): Madeleine Creevy McNally

Licensing Company Email: XLI@slsny.com DR Email: mcreevy@xttrium.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☒ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer - Own Label
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☒ Others: Human OTC	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?	X	
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
2/18/2000		ID		Shoshone

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CR-2000-0032465	State of Idaho

Reason/Charge
Possession of marijuana

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Madeleine Creevy McNally	

Name of Business/Industry/Entity

Provide explanation below:

Please see attached documents

Madeleine Creevy McNally

Original Signature (electronic, copies or stamps not accepted)

02/24/2026

Date

Maria Herrera

From: Compliance Department <compliance@slsnysupport.com>
Sent: Friday, June 12, 2026 11:54 AM
To: Maria Herrera
Subject: Re: [#312036] Nevada Out-of-State Wholesaler Application-Xttrium Laboratories, Inc.
Attachments: XLI-MP-FDA 483-Inspection Dates 6-9-25 to 6-18-25-REDACTED-Use 1st.pdf

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

From: State License Servicing, Inc.

Subject: Nevada Out-of-State Wholesaler Application-Xttrium Laboratories, Inc.

Ticket Number 312036

Dear Licensing Board,

I hope this finds you well.

As per our phone call conversation, please see attached FDA 483 form for our client's facility (WH01653) in Mount Prospect, IL 60056. Their facility for this initial application (3400 West Lake Avenue) is not FDA registered nor Inspected.

Could you please confirm receipt and that it suffices?

Thanks in advance for your time and assistance.

Kind Regards,

Ramon Rivera
Information Systems
Pharmaregs, Inc.
State License Servicing, Inc
CIM 90, Carr. 165, Suite C-102
Guaynabo, PR 00968
(814)-350-7298

On Thu, 11 Jun at 3:12 PM , NV Contact Maria Herrera <m.herrera@pharmacy.nv.gov> wrote:

From: Maria Herrera
Sent: Thursday, June 11, 2026 12:09 PM
To: 'Christine Cannon Licensing' <christine.cannon@slslicensing.com>
Subject: RE: [#312036] Nevada Out-of-State Wholesaler Application-Xttrium Laboratories, Inc.

Hi Christine,

Please provide a copy of the 2025 483 form issued by the FDA and the responses, also confirm if the FDA has re-inspected and closed the audit.

Kind Regards,
Maria H.

From: Christine Cannon Licensing <christine.cannon@slslicensing.com>
Sent: Wednesday, June 10, 2026 8:52 AM
To: Maria Herrera <m.herrera@pharmacy.nv.gov>
Subject: Re: [#312036] Nevada Out-of-State Wholesaler Application-Xttrium Laboratories, Inc.

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

From: State License Servicing, Inc.

Subject: Nevada Out-of-State Wholesaler Application-Xttrium Laboratories, Inc.

Ticket Number 312036

Dear Licensing Board,

I hope this finds you well.

In regards to the request received for our client's **Xttrium Laboratories, Inc.** initial application for their facility located at: **3400 West Lake Avenue, Glenview IL 60026**. Please keep in mind this facility is not FDA inspected. See attached their most recent home state inspection report.

Could you please confirm receipt of the above and that it suffices?

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Chicago District Office 550 West Jackson Blvd., Suite 800 Chicago, IL 60661- 4716 312-596-4200 Fax: 312-353-5863	06/09/2025 – 06/18/2025* FEI NUMBER 3008436464
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Madeleine Creevy, Executive Vice President	
FIRM NAME Xttrium Laboratories, Inc.	STREET ADDRESS 1400 E Business Center Dr, Suite 100
CITY, STATE, ZIP CODE, COUNTRY Mount Prospect, IL 60056	TYPE ESTABLISHMENT INSPECTED API and Finished Product Drug Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM, I/WE OBSERVED:

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

a) Your firm utilizes a reference standard (ERA USP System Suitability Set – 40 mL) for the system suitability testing of your TOC analyzer LE-001-TOC. This product requires refrigerated storage condition. However, your firm stored the reference standard ([redacted]) in a refrigerator that was not qualified. Prior to our arrival in the QC department, your firm removed the reference standard from the refrigerator and informed us that it was removed for system suitability testing. However, your QC chemist later stated that no system suitability testing was planned for the day. Upon our request regarding the storage location for the reference standard, your firm provided multiple instances of misinformation. Your personnel even led us to an area purportedly to show us the refrigerator for the reference standard storage, but no refrigerator was found at that location. Finally, your QC chemist admitted that she had removed the reference standard from an unqualified refrigerator at the request of [redacted] prior to our arrival.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Tyler P Supreet K Sran	Tyler M Peterson, Investigator Nibin Varghese, Investigator Ramia Brzenjy, Investigator Supreet K Sran, Investigator	06/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Chicago District Office 550 West Jackson Blvd., Suite 800 Chicago, IL 60661- 4716 312-596-4200 Fax: 312-353-5863	06/09/2025 – 06/18/2025* FEI NUMBER 3008436464
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Madeleine Creevy, Executive Vice President	
FIRM NAME Xttrium Laboratories, Inc.	STREET ADDRESS 1400 E Business Center Dr, Suite 100
CITY, STATE, ZIP CODE, COUNTRY Mount Prospect, IL 60056	TYPE ESTABLISHMENT INSPECTED API and Finished Product Drug Manufacturer

b) Your firm utilizes a standalone pH meter ID # LE-0005 for the pH analysis for raw materials, in process, finished product etc. During our review of the electronic data, we observed that multiple analyses of single samples were performed without proper documentation. These repeated analyses were not recorded in the analyst's laboratory notebook. Your QC personnel admitted to discarding printouts from the repeated analyses without recording the data. This practice raises significant concerns about data integrity and the reliability of your pH testing procedures. Following are the examples, we observed but are not limited to:

1. On 05/22/2025, your QC Chemist performed pH analysis for sample #3 two times according to the electronic record for Amantadine, [redacted] Your QC chemist recorded only the second analysis details in the lab notebook. Your QC chemist stated that, she discarded the printout and did not record the result in the lab notebook. She further stated that, her supervisor was aware of this situation.

2. On 06/07/2025, your QC Chemist performed pH analysis for sample #9 three times according to the electronic record for Chlorhexidine Gluconate Solution, USP 20%, [redacted] Your QC chemist recorded only third analysis details in the lab notebook. Your QC chemist stated that, she discarded the printout and did not record the initial results in the lab notebook.

Additionally, a review of your laboratory logbook for equipment LE-0005 showed no verification had been completed by the responsible person since 05/14/2025. This lapse in verification raises concerns about the reliability of data generated using this equipment.

This is a repeat observation.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Tyler Peterson Supreet K. Sran	Tyler M Peterson, Investigator Nibin Varghese, Investigator Ramia Brzenjy, Investigator Supreet K Sran, Investigator	06/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Chicago District Office 550 West Jackson Blvd., Suite 800 Chicago, IL 60661- 4716 312-596-4200 Fax: 312-353-5863	06/09/2025 – 06/18/2025* FEI NUMBER 3008436464
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Madeleine Creevy, Executive Vice President	
FIRM NAME Xttrium Laboratories, Inc.	STREET ADDRESS 1400 E Business Center Dr, Suite 100
CITY, STATE, ZIP CODE, COUNTRY Mount Prospect, IL 60056	TYPE ESTABLISHMENT INSPECTED API and Finished Product Drug Manufacturer

OBSERVATION 2

Records maintained of any modification of an established method employed in testing do not include the reason for the modification and the data to verify that the modification produced results that are at least as accurate and reliable for the material being tested as the established method.

Specifically,

Your firm's current audit trail review process does not include clear procedures for a comprehensive evaluation of critical audit trail data elements including but not limited to changes to integration parameters, manual integrations, method modifications, instrument configuration changes, etc. During our inspection, one your Quality Chemist who is responsible for audit trail reviews informed us that their audit trail review is limited to verifying whether methods are attached to data packages or not. This narrow scope falls significantly short of a thorough and effective audit trail review. Your firm follows *SOP No: QC SOP 167-0: Operating Procedure for the HPLC and GC Using Agilent's OpenLab Software* for the audit trail review process. However, this SOP is deficient in defining comprehensive audit trail review procedures. The lack of detailed guidance in the SOP contributes to the inadequacy of your firm's audit trail review practices. As an example of these deficiencies, an adequate audit trail review was not completed for the analytical package of 0.12% Chlorhexidine Oral Rinse, [redacted] This instance further illustrates the systemic nature of the problem in your audit trail review process.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Tyler Peterson Supreet Kaur	Tyler M Peterson, Investigator Nibin Varghese, Investigator Ramia Brzenjy, Investigator Supreet K Sian, Investigator	06/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Chicago District Office 550 West Jackson Blvd., Suite 800 Chicago, IL 60661- 4716 312-596-4200 Fax: 312-353-5863	06/09/2025 – 06/18/2025* FEI NUMBER 3008436464
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Madeleine Creevy, Executive Vice President	
FIRM NAME Xttrium Laboratories, Inc.	STREET ADDRESS 1400 E Business Center Dr, Suite 100
CITY, STATE, ZIP CODE, COUNTRY Mount Prospect, IL 60056	TYPE ESTABLISHMENT INSPECTED API and Finished Product Drug Manufacturer

OBSERVATION 3

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

Your firm failed to exercise appropriate controls over your computers and related system to assure that changes in the records are instituted only by authorized personnel. Following are the examples for the lack of control on the electronic system, but are not limited to:

a) You firm utilizes a standalone Easy R40 Refractometer (MP-REF-01) to measure the refractive index of raw materials. For example, on 04/01/2025 this instrument was used for the refractive index measurement of Isopropyl Alcohol [redacted]. The system allows users to log in without entering a password, despite having the capability to create up to eight (8) unique usernames. This lack of user authentication compromises data integrity and traceability. The instrument has a limited data storage capacity of 20 entries, after which it overwrites previous results. This practice potentially leads to the loss of critical data. Your firm has failed to establish and follow procedures for reviewing the electronic data generated by this instrument. The accuracy of data recorded on associated laboratory notebooks has not been verified by your quality unit. There is no evidence of a systematic process for backing up the electronic data generated by the Easy R40 Refractometer risking permanent loss of important analytical data.

b) D30 Density Meter (MP-DEN-01) for density determination of raw materials and finished products. For example, on 05/30/2025 this instrument was used for the density determination of Lactulose, [redacted] The system allows users to log in without entering a username or password. This

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Tyler Peterson Supreet K Sran	Tyler M Peterson, Investigator Nibin Varghese, Investigator Ramia Brzenjy, Investigator Supreet K Sran, Investigator	06/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Chicago District Office 550 West Jackson Blvd., Suite 800 Chicago, IL 60661- 4716 312-596-4200 Fax: 312-353-5863	06/09/2025 – 06/18/2025* FEI NUMBER 3008436464
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Madeleine Creevy, Executive Vice President	
FIRM NAME Xttrium Laboratories, Inc.	STREET ADDRESS 1400 E Business Center Dr, Suite 100
CITY, STATE, ZIP CODE, COUNTRY Mount Prospect, IL 60056	TYPE ESTABLISHMENT INSPECTED API and Finished Product Drug Manufacturer

lack of user authentication compromises data integrity and traceability. The instrument has a limited data storage capacity of 20 entries, after which it overwrites previous results. This practice potentially leads to the loss of critical data. Your firm has failed to establish and follow procedures for reviewing the electronic data generated by this instrument. The accuracy of data recorded on associated laboratory notebooks has not been verified by your quality unit. There is no evidence of a systematic process for backing up the electronic data generated by the D30 Density Meter, risking permanent loss of important analytical data.

c) Your firm utilizes an UV Spectrophotometer (MP 1662 to perform identification test for raw materials and finished products. For example, on 06/05/2025 this instrument was used for dissolution sample analysis for Megestrol Acetate Oral Suspension, USP [redacted] The system allows users to log in without entering a password. This lack of user authentication compromises data integrity and traceability, potentially allowing unauthorized access to the system. I observed that primary data is stored on a local drive. According to your firm's written procedure *SOP No: IT SOP 5-3: IT Backup Policy, Effective Date 04/24/2025*, daily backups are conducted at 6:00 am every day. The delete function is enabled in this system, allowing for the potential unauthorized deletion or alteration of data. The lack of user authentication could lead to unauthorized changes to data or methods. While daily backups are performed, the interim period between backups leaves data vulnerable to loss or unauthorized changes.

d) Your standalone pH meters (ID # LE-0005 & ID # LE-0006) has storage capacity to store data up to 250 analyses, after which system overwrites previous results. This practice potentially leads to the loss of critical data. Your firm has failed to establish and implement a procedure for backing up the data from these pH meters.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Tyler Peterson Supreet K Sran	Tyler M Peterson, Investigator Nibin Varghese, Investigator Ramia Brzenjy, Investigator Supreet K Sran, Investigator	06/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Chicago District Office 550 West Jackson Blvd., Suite 800 Chicago, IL 60661- 4716 312-596-4200 Fax: 312-353-5863	06/09/2025 – 06/18/2025* FEI NUMBER 3008436464
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Madeleine Creevy, Executive Vice President	
FIRM NAME Xttrium Laboratories, Inc.	STREET ADDRESS 1400 E Business Center Dr, Suite 100
CITY, STATE, ZIP CODE, COUNTRY Mount Prospect, IL 60056	TYPE ESTABLISHMENT INSPECTED API and Finished Product Drug Manufacturer

e) Your firm lacks adequate control over the issuance of and access of blank batch records. We observed that copies of blank batch records are stored on a SharePoint site where approximately 94 individuals have print access. This includes individuals from operations, packaging, warehouse, and shipping/receiving departments. Your firm informed us that the quality unit issues batch records and other controlled document. I observed that Quality issued documents with a stamp stating "Printed/Issued by/date". However, on 06/10/2023, we observed a blank form "Document QC079A" issued to QC without any issuance stamp.

This is a repeat observation.

OBSERVATION 4

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been distributed.

Specifically,

Your firm failed to review and investigate aborted chromatographic injections as recorded in the OpenLab CDS System Activity Log Detailed Report. From 03/01/2024 to 06/16/2025 there were approximately 568 aborted injections, including both user-initiated aborts and hardware errors, which are not thoroughly reviewed or investigated. Following are the examples, but are not limited to:

a. On 03/01/2024 at 16:38, user [redacted] aborted a post-run for standard [redacted] The post-run was started at 16:31 as part of system suitability. According to your written procedure *SOP No: QC SOP No.71-16: HPLC Analysis of Parachloroaniline in Chlorhexidine Gluconate Raw Materials, In-*

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Tyler Peterson Supreet K. Sran	Tyler M Peterson, Investigator Nibin Varghese, Investigator Ramia Brzenjy, Investigator Supreet K Sran, Investigator	06/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Chicago District Office 550 West Jackson Blvd., Suite 800 Chicago, IL 60661- 4716 312-596-4200 Fax: 312-353-5863	06/09/2025 – 06/18/2025* FEI NUMBER 3008436464
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Madeleine Creevy, Executive Vice President	
FIRM NAME Xttrium Laboratories, Inc.	STREET ADDRESS 1400 E Business Center Dr, Suite 100
CITY, STATE, ZIP CODE, COUNTRY Mount Prospect, IL 60056	TYPE ESTABLISHMENT INSPECTED API and Finished Product Drug Manufacturer

Process and Finished Products, Effective Date 07/20/2020, the run time is 3 minutes and post-run time is 12 minutes. Your analyst informed us that his supervisor instructed him to abort the post-run.

b. On 05/16/2025 at 11:59, user [redacted] aborted "Sequence: [redacted] – Aborted Injection 5-GC072025-16 11-55-42-05-00RS.dx". System suitability was failed during the standard verification. System suitability was failed for injection #5. Your firm repeated the system suitability without any justification. Your analyst failed to record the system suitability failure in the laboratory notebook and invalidated data logbook according to your written procedure *SOP No: QC SOP 166-0: Chromatographic Guideline for HPLC and GC, Effective Date 07/12/2024.*

c. On 05/14/2025 at 14:23 user [redacted] aborted "Sequence: [redacted] – Aborted Injection 5 – 2025-05-14 13-53-15-00-03.dx." System suitability for working standard A was failed for Injection 5. Your analyst failed to record the system suitability failure in invalidated data logbook according to your written procedure.

Additionally, according to your firm's procedures, these aborted runs should be recorded in Form 000003 - *Invalidated HPLC and GC Chromatogram Logbook* and reviewed by a supervisor. However, I observed that your firm is not consistently recording these aborted results in Form 000003. For the year of 2024 and 2025 your firm only recorded approximately 98 aborted runs. These unreviewed aborted injections could potentially impact data integrity and product quality.

OBSERVATION 5

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
SEE REVERSE OF THIS PAGE	Tyler Peterson Supreet K Sran	Tyler M Peterson, Investigator Nibin Varghese, Investigator Ramia Brzenjy, Investigator Supreet K Sran, Investigator	06/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Chicago District Office 550 West Jackson Blvd., Suite 800 Chicago, IL 60661- 4716 312-596-4200 Fax: 312-353-5863	06/09/2025 – 06/18/2025* FEI NUMBER 3008436464
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Madeleine Creevy, Executive Vice President	
FIRM NAME Xttrium Laboratories, Inc.	STREET ADDRESS 1400 E Business Center Dr, Suite 100
CITY, STATE, ZIP CODE, COUNTRY Mount Prospect, IL 60056	TYPE ESTABLISHMENT INSPECTED API and Finished Product Drug Manufacturer

Written procedures for the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures are not followed.

Specifically,

During our walkthrough inspection on 06/13/2025, the following deficiencies were observed in the incoming material receiving process, but are not limited to:

a. The incoming shipment inspection log for trailer inspection and disposition was not completed for item code 16H1BBTL for lots [redacted] and [redacted] The material was received into your firm's ERP system - Sage100.

b. Lot numbers were not accurately transcribed from the manufacturer's paperwork into ERP system - Sage100, for example, receiving Ticket Number [redacted] from Sage100 lists Lot [redacted] but the correct supplier lot number is [redacted]

c. For multiple lots of incoming material (Lot numbers [redacted] that were delivered to the QC Lab, the "received by" documentation was missing entirely. These lots were tested by the laboratory and subsequently released in the system despite the incomplete receiving documentation.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Tyler Peterson Supreet K. Sran	Tyler M Peterson, Investigator Nibin Varghese, Investigator Ramia Brzenjy, Investigator Supreet K Sran, Investigator	06/18/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Chicago District Office 550 West Jackson Blvd., Suite 800 Chicago, IL 60661- 4716 312-596-4200 Fax: 312-353-5863	06/09/2025 – 06/18/2025* FEI NUMBER 3008436464

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Madeleine Creevy, Executive Vice President	
FIRM NAME Xttrium Laboratories, Inc.	STREET ADDRESS 1400 E Business Center Dr, Suite 100
CITY, STATE, ZIP CODE, COUNTRY Mount Prospect, IL 60056	TYPE ESTABLISHMENT INSPECTED API and Finished Product Drug Manufacturer

OBSERVATION 6

Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions.

Specifically,

On 06/10/2025, during a review of training records for QC chemist [redacted] and the corresponding laboratory notebook, I observed the following discrepancy: [redacted] began performing pH analysis prior to the completion of required training. Training was signed off on 04/05/2024; however, [redacted] started conducting analyses on 03/19/2024. According to *SOP No. QA SOP 11-12: "Employee Training Program" (Effective Date: 05/26/2022)*, both the trainee and trainer are required to sign and date the training record upon completion of training. This instance demonstrates a failure to adhere to established training procedures and indicates that the training was either ineffective or not properly implemented, potentially compromising data integrity and the quality of laboratory operations. This observation highlights the need for stricter adherence to training protocols and improved oversight of personnel qualifications before allowing them to perform analytical procedures.

*** DATES OF INSPECTION**
06/09/2025 (Mon), 06/10/2025 (Tue), 06/11/2025 (Wed), 06/12/2025 (Thu), 06/13/2024 (Fri), 06/16/2025 (Mon), 06/17/2025 (Tue), and 06/18/2024 (Wed).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Tyler M Peterson, Investigator Nibin Varghese, Investigator Ramia Brzenjy, Investigator Supreet K Sran, Investigator	06/18/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

WHOLESALE DRUG DISTRIBUTOR INSPECTION

BUSINESS NAME			INSPECTION NUMBER
Xttrium Laboratories Inc			
ADDRESS			LICENSE NUMBER
3400 W. Lake Ave.			004.005708
CITY	COUNTY	TELEPHONE NUMBER (include Area Code)	DATE
Glenview	Cook	(773) 268-5800	11-20-25
ICSA LICENSE	EXPIRATION DATE	FAX NUMBER (include Area Code)	INSPECTOR ID
N/A	12-31-26	( )	JKirby
DEA LICENSE	EXPIRATION DATE	TYPE OF LICENSE	
N/A		WDD - Legend and OTC	
PERSON(S) RESPONSIBLE FOR DRUGS		*EMERGENCY TELEPHONE NUMBER*	
Madeleine Creevy McNally		[redacted]	
		(773) 268-5800 (work)	

VIOLATIONS		YES	NO
8301.25(a)	All wholesale distributors must have valid license.	X	
1510.50(i)	Must comply with all Federal, State & Local laws.	X	
8301.25(e)(1)	Acceptable storage & handling conditions and standards.	X	
1510.50(a)	(1) Facility is of suitable size (2) Storage area meets requirements (3) Quarantine area is separate, distinct from general area (4) Maintained in clean & orderly condition (5) Free from infestation by insects, rodents, birds or vermin	X	
1510.50(c)	Drugs are stored under proper temperature and humidity conditions. (1) Room temperature is controlled (2) Temperature& humidity equipment to document storage conditions.	X	
8301.25(e)(2)	Minimum liability and other insurance.	x	
8301.25(e)(3)	Must have acceptable security system.	X	
1510.50(b)(1)	Secure from unauthorized entry (a) Limited& well-controlled access from outside the premises. (b) Outside perimeter is well-lighted. (c) Prescription drug area limited to authorized personnel.	X	
(2)	Alarm system to detect after hour entry.		
(3)	Protection against theft & diversion.		
8301.25(e)(4)	Records shall be maintained for 2 years.	X	
1510.50(f)	(1) Records& inventories for receipt, distribution, disposal. (a) Source of drugs & location from where shipped.	X	

VIOLATIONS		YES	NO
	(b) Identify & quantity of drugs received, distributed, disposed of. (c) Dates of receipt, distribution, disposal. (2) Inventories & records area available for inspection and copying. (3) Records are stored at site off-site location	X	
8301.25(e)(5)	Personnel must be qualified.	X	
1510.50(h)	List of persons responsible & duties is maintained.	X	
8301.25(e)(7)	Written Policies& procedures are maintained.	X	
1510.50(g)(1)	(1) Procedure to rotate stock. (2) Procedure for recalls & withdrawals of drugs. (a) FDA or other law enforcement action. (b) Manufacturer recall. (c) Replacement action. (3) Procedures for crisis (fire, flood, etc.) (4) Procedures to remove, segregate & document disposition of outdates.	X	
(e)	(1) Drugs are quarantined & physically separated (outdates, damaged, etc.) (2) Drugs are quarantined that have been used or are open.		
8301.25(e)(8)	Inspection procedures for all incoming and outgoing drug shipments.	X	
1510.50(d)	(1) Visual examination upon receipt for damage. (2) Outgoing shipments are inspected to prevent outdates or deteriorated. (3) Records are maintained.	X	

INVESTIGATOR'S SIGNATURE	LICENSEE'S SIGNATURE	SUPERVISOR'S SIGNATURE AND DATE
11-20-25	11-20-25	

IL486-1777 3/96(ENF)

WHOLESALE DRUG DISTRIBUTOR INSPECTION (NARRATIVE)

BUSINESS NAME			INSPECTION NUMBER
Xttrium Laboratories Inc			
ADDRESS			LICENSE NUMBER
3400 W Lake Ave.			004.005708
CITY	COUNTY	TELEPHONE NUMBER (include Area Code)	DATE
Glenview	Cook	(773) 268-5800	11-20-25
ICSA LICENSE	EXPIRATION DATE	FAX NUMBER (include Area Code)	INSPECTOR ID
N/A	12-31-26	( )	JKirby

Inspection pursuant to the receipt of an new WDD application for Legend and OTC products. WebEx held on 11-20-25.

Prior to inspection, the following documents were obtained from the applicant:

1. WDD Questionnaire
2. Building Schematic
3. Org Charts
4. Madeleine Creevy McNally Resume
5. Liability Insurance Coverpage
6. Required SOP's

Note: Crisis policy discussed and will be updated.

Sage 100 ERP System - Both electronic and paper records. Continuous migration to more elctronic records. Plan to store archive records off-site at Iron Mountain

Contract with Orkin - Monthly

Reverse Distributor - Emco (primary) InMar (secondary)

Temp/Humidity Monitoring: Dixon (continuous 24/7 electronic monitoring) 32 devices in the building

Building has exterior lighting - 12 man doors - 20 dock doors - windows are located in front and back offices but not in warehouse areas

Warehouse has 5 Zones. Zone 1 is quarantine only.

Glenview PD and Fire respond to the alarm.

Johnson Controls Security System - Codes will be unique to each person, keycard access in the building, 15 cameras, 15 motion senors, and 15 glass break sensors

Employee training discussed

License is approved for release/activation.

BEFORE THE GEORGIA STATE BOARD OF PHARMACY
STATE OF GEORGIA

IN THE MATTER OF:	)	
	)	
Xttrium Laboratories Inc.,	)	**DOCKET NO.**
Applicant No. 1967891	)	
License No. PHMA000308,	)	
	)	
Respondent.	)	

GEORGIA STATE BOARD OF PHARMACY
FEB 18 2026
DOCKET NO. 2026-0009

PUBLIC CONSENT ORDER

By agreement of the Georgia State Board of Pharmacy ("Board") and Xttrium Laboratories Inc. ("Respondent"), the following disposition of this matter is entered pursuant to the provisions of O.C.G.A. T. 26, Ch. 4, and the Georgia Administrative Procedure Act, O.C.G.A. § 50-13-13(a)(4), as amended.

FINDINGS OF FACT

1.

Respondent was issued a license to operate as a manufacturing pharmacy in the State of Georgia on August 13, 2010, with an expiration of June 30, 2027. Respondent's license is currently active. Respondent holds an active wholesale distributor license in Illinois.

2.

Respondent is based in Illinois and specializes in the sale of prescription Oral Rinse to retail chains, shipping to several states, including Georgia.

3.

On or about November 13, 2025, the Board received an application for change of ownership by Respondent, dated November 7, 2025. The application indicated the change of ownership occurred on July 1, 2024. The application also listed Respondent's license type as a wholesale distributor license, rather than a manufacturing pharmacy license, which is the license type currently active with the Board.

4.

Board Rule 480-7-.01(5) 480-7-.03(d) apply to manufacturing pharmacies and wholesale distributors, respectively. Under these rules, prior to any change in name, ownership, mode of operation or location of a pharmacy, a licensee must apply for approval of such change by submitting a Board-approved application to the Board and paying the required fee. Applications must be made and approved prior to the change.

5.

In a statement to the Board, Respondent explains that due to the company's expansion, a management error was committed of not systematically and comprehensively applying for all required state licenses and some state applications were filed late. This led to the several states initiating disciplinary actions beginning in 2007 through 2011. On September 22, 2025, Respondent provided the Board with a subsequent statement explaining the most recent citation notice issued on September 15, 2025, by the Utah State Board of Pharmacy ("Utah Board"). The Utah Board issued Respondent a citation for failure to timely report a change of ownership that became effective on July 1, 2024, on August 20, 2025, violating their rule requiring licensees report the change no later than ten (10) business days before the date of change Respondent explains that the previous designated representative transitioned his day-to-day operations to his son and daughter. Since the transition, Respondent explains they have taken steps to comply with state licensing by hiring an outside firm specializing in the application and maintenance of state licenses to ensure compliance with all state regulations.

6.

Respondent neither admits nor denies the above findings of fact, and waives any further findings of fact with respect to the above-styled matter.

CONCLUSIONS OF LAW

Under O.C.G.A. T. 26, Ch. 4, the Georgia State Board of Pharmacy is authorized to discipline Respondent's license to operate as a pharmacy for the conduct stated above. Respondent waives any further conclusions of law with respect to this matter.

ORDER

The Board, having considered the particular facts and circumstances of this case, hereby ORDERS, and Respondent hereby AGREES, that Respondent's license shall be disciplined as follows:

1.

Respondent shall submit to the Board a fine in the amount of **Five Thousand Dollars ($5,000.00)** for failure to report ownership change prior to change, in violation of Board Rules. Such fine shall be payable within **sixty (60) days** from the effective date of this Public Consent Order. Payment shall be in the form of a cashier's check or money order made payable to the Georgia State Board of Pharmacy and sent to: Georgia State Board of Pharmacy, Attention: Executive Director, 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, Georgia 30334. Respondent's failure to pay the fine by the sixtieth day shall subject Respondent's license to further disciplinary action, including revocation.

2.

This Consent Order and dissemination thereof shall serve as a **PUBLIC REPRIMAND** to the Respondent for Respondent's conduct.

3.

Approval of this Public Consent Order by the Georgia State Board of Pharmacy shall in no way be construed as condoning the Respondent's alleged conduct, and shall not be construed as a waiver of any of the lawful rights possessed by the Board.

4.

Respondent acknowledges that Respondent has read this Public Consent Order and understands its contents. Respondent understands that this Public Consent Order will not become effective until approved and docketed by the Georgia State Board of Pharmacy. Respondent further understands and agrees that the Board shall have the authority to review the investigative file and all relevant evidence in considering this Public Consent Order. Respondent understands that this Consent Order, once approved and docketed, shall constitute a public record, evidencing disciplinary action by the Board. Respondent further understands that if this Public Consent Order is not approved, it shall not constitute an admission against interest in this proceeding or prejudice the ability of the Board to adjudicate this matter. Respondent consents to the terms and sanctions contained herein.

Approved by the Board, this 18th day of February, 2026.

GEORGIA STATE BOARD OF PHARMACY

BY: _____

~~CECIL N. CORDLE, Pharm D.~~

President

Young Chang, R.Ph

[Signatures on Following Page]

ATTEST:

J. CLINTON JOINER, II
Executive Director

(BOARD SEAL)



CONSENTED TO:

AGENT
Printed Name: MADELEINE CREEVY McNALLY
ON BEHALF OF
Respondent
Xttrium Laboratories, Inc.

AS TO SIGNATURE OF AGENT ON BEHALF OF RESPONDENT
Sworn to and subscribed before me
this 21st day of JANUARY, 2026.

Vijay Verma
NOTARY PUBLIC
My commission expires: 04/28/2029

OFFICIAL SEAL
VIJAY KUMAR VERMA
Notary Public, State of Illinois
Commission No 1009228
My Commission Expires April 28, 2029

D: Sc. pl. ne Summary

Xttrium Laboratories
Revised January 21st, 2026
Discipline Summary

Company Background

Xttrium Laboratories is a manufacturing company in existence in Chicago since 1939. For the last 38 years, Xttrium's products have been surgical setting antiseptics with an active ingredient of Chlorhexidine Gluconate (CHG), classified as a drug by the FDA. These antiseptic products have been sold in Illinois to all major hospital supply wholesalers in the US. Foreign state licenses were not required.

In 2004, Xttrium began marketing a prescription Oral Rinse product for gum disease with the same CHG active ingredient, a product similar to Peridex. Customers were originally the same wholesale hospital suppliers. Over the last twenty one years, Xttrium began selling prescription Oral Rinse to the major retail drug chains. Delivery sites expanded to all states. With the expansion, the management error was committed of not systematically and comprehensively applying for all required state licenses. Consequently, some state applications were filed late.

State Disciplinary Actions Results

Due to the late filings, the states of Missouri, Colorado and Alabama began disciplinary actions. In a settlement, Missouri issued a probationary license in 2007 for which probation expires in June 2010. The Colorado action was dropped and the state issued an unrestricted license upon the expiration of the Missouri probation in June 2010. There is no disciplinary history in Colorado. The Alabama action was settled with payment of a $500 fine in April 2009. A consent order stemming from a Rhode Island complaint was signed in December, 2011.

Xttrium has had additional disciplinary actions in 2025 in the State of Utah, Maryland and Georgia. All of these citations were related for a failure to notify the state of a change of ownership event according to their procedures. The state of Utah requires 10 days in advance notification before the change of ownership occurs. Xttrium paid the fine for the state of Utah for $1,050 (October 2025). The state of Maryland requires 30 days notification after the change of ownership event. Xttrium paid the fine for the State of Maryland for $5,000 (January 2026). The State of Georgia requires notification of change of ownership prior to the change. Xttrium paid the fine for the state of Georgia for $5,000 (January 2026).

Current Procedures

Xttrium has since initiated a formal process of state license preparation. An outside firm, specializing in the application and maintenance of state licenses, State Licensing Servicing, LLC, has been hired to prepare the needed forms within due dates. An attorney who specializes in state licensing has been retained to review the filings on a recurring basis. The Senior Vice President of Commercial Operations is now working directly with SLS to ensure compliance to all state regulations.

FDA Regulation

Xttrium is inspected by the FDA on a regular basis. For each inspection, any remedies required are completed on time and then approved by the FDA. The most recent inspection was from June 9, 2025 to June 18, 2025. A form 483 was issued with 6 observations. On July 11, 2025, Xttrium responded with the correction action plan for the Observations. All remediation activities were completed by Xttrium in November 2025. This audit has not been formally closed out by the FDA. The FDA will re-inspect Xttrium in 2026 and close out the audit at that time.

Prior to the June 2025 audit, there was an FDA inspection was from February 27, 2024 to March 8, 2024. A Form 483 was issued with 7 Observations. On March 29, 2024, Xttrium responded with the corrections to the Observations. The changes were executed and no additional action was required by the FDA.

Licensed By Home State of Illinois

Xttrium has been licensed as a manufacturer and wholesaler in its home state of Illinois at all times since the company began production and sale of regulated drugs.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

*Please see attached discipline summary

M.C. McNally Madeleine Creevy McNally

Original Signature (electronic, copies or stamps not accepted)

02/24/2026

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Encora
Address: 1 West First Ave. City: Conshohocken State: PA Zip: 19428
Name: McKesson Corp.
Address: 6555 State Highway 161 City: Irving State: TX Zip: 75039
Name: Cardinal Health
Address: 7000 Cardinal Pl. City: Dublin State: OH Zip: 43017
Name: Medline
Address: Three Lakes Dr. City: Northfield State: IL Zip: 60093

N/A

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): N/A
Corporation/Organization Name: Xttrium Laboratories, Inc.
Mailing Address: c/o State License Servicing, Inc. 225 Dolson Avenue, 4th Floor
City: Middletown State: NY Zip: 10940
Telephone: [redacted] Email: XLI@slsny.com
Contact Person Name: Christine Cannon

N/A

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

N/A

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: Drug Labeler code : 0116	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Xttrium Laboratories, Inc.

Facility Name

Madeleine Creevy McNally

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

02/24/2026

Date

Board Use Only	Date Received: 3/9/26	Amount: $1000ck 50596

Labeler Code

/ NDC (index.cfm)

National Drug Code Directory

Current through February 19, 2026

You have searched Finished drug products

Search Results: *'0116'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
Acclean Chlorhexidine Gluconate 0.12% Oral Rinse	0116-4075-01	1.2 mg/mL	LIQUID	ORAL	ANDA077789	Xttrium Laboratories, Inc	0116-4075	Chlorhexidine Gluconate 0.12% Oral Rinse	CHLORHEXIDINE GLUCONATE	HUMAN PRESCRIPTION DRUG	10/01/2009	N/A	ANDA	473 mL in 1 BOTTLE (0116-4075-01)	Decreased Cell Wall Integrity [PE]
Acclean Chlorhexidine Gluconate 0.12% Oral Rinse	0116-6720-04	1.2 mg/mL	LIQUID	ORAL	ANDA077789	Xttrium Laboratories, Inc	0116-6720	Chlorhexidine Gluconate 0.12% Oral Rinse	CHLORHEXIDINE GLUCONATE	HUMAN PRESCRIPTION DRUG	08/22/2016	N/A	ANDA	118 mL in 1 BOTTLE (0116-6720-04)	Decreased Cell Wall Integrity [PE]
Amantadine	0116-4010-16	50 mg/5mL	SOLUTION	ORAL	ANDA075060	Xttrium Laboratories, Inc	0116-4010	Amantadine	AMANTADINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/05/2024	N/A	ANDA	473 mL in 1 BOTTLE (0116-4010-16)	Influenza A M2 Protein Inhibitor [EPC], M2 Protein Inhibitors [MoA]
Amantadine	0116-4010-41	50 mg/5mL	SOLUTION	ORAL	ANDA075060	Xttrium Laboratories, Inc	0116-4010	Amantadine	AMANTADINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	11/05/2024	N/A	ANDA	100 TRAY in 1 CASE (0116-4010-41) / 10 CUP, UNIT-DOSE in 1 TRAY / 10 mL in 1 CUP, UNIT-DOSE (0116-4010-10)	Influenza A M2 Protein Inhibitor [EPC], M2 Protein Inhibitors [MoA]
Antiseptic Skin Cleanser	0116-0115-37	4 mg/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc	0116-0115	Chlorhexidine Gluconate 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	02/20/2014	N/A	NDA	237 mL in 1 BOTTLE, PLASTIC (0116-0115-37)	Decreased Cell Wall Integrity [PE]
Antiseptic Skin Cleanser	0116-0137-34	4 mg/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc	0116-0137	Chlorhexidine Gluconate 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	04/01/2013	02/28/2027	NDA	237 mL in 1 BOTTLE, PLASTIC (0116-0137-34)	Decreased Cell Wall Integrity [PE]
Antiseptic Skin Cleanser	0116-0137-43	4 mg/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc	0116-0137	Chlorhexidine Gluconate 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	01/01/2019	01/31/2027	NDA	473 mL in 1 BOTTLE (0116-0137-43)	Decreased Cell Wall Integrity [PE]
Antiseptic Skin Cleanser	0116-0161-08	4 mg/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc	0116-0161	Chlorhexidine Gluconate 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	05/01/2011	N/A	NDA	237 mL in 1 BOTTLE, PLASTIC (0116-0161-08)	Decreased Cell Wall Integrity [PE]
Antiseptic Skin Cleanser	0116-0161-15	4 mg/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc	0116-0161	Chlorhexidine Gluconate 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	01/01/2017	N/A	NDA	15 mL in 1 KIT (0116-0161-15)	Decreased Cell Wall Integrity [PE]
Antiseptic Skin Cleanser	0116-0161-16	4 mg/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc	0116-0161	Chlorhexidine Gluconate 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	05/01/2011	N/A	NDA	472 mL in 1 BOTTLE, PUMP (0116-0161-16)	Decreased Cell Wall Integrity [PE]
Antiseptic Skin Cleanser	0116-0162-08	4 mg/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc	0116-0162	Chlorhexidine Gluconate 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	01/01/2014	N/A	NDA	237 mL in 1 BOTTLE, PLASTIC (0116-0162-08)	Decreased Cell Wall Integrity [PE]

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
Antiseptic Skin Cleanser	0116-0228-00	4 mg/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0228	Chlorhexidine Gluconate 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	10/30/2012	N/A	NDA	237 mL in 1 BOTTLE, PLASTIC (0116-0228-00)	Decreased Cell Wall Integrity [PE]
Antiseptic Skin Cleanser	0116-0228-16	4 mg/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0228	Chlorhexidine Gluconate 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	01/01/2019	N/A	NDA	473 mL in 1 BOTTLE, PLASTIC (0116-0228-16)	Decreased Cell Wall Integrity [PE]
Antiseptic Skin Cleanser	0116-0237-01	4 mg/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0237	Chlorhexidine Gluconate 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	02/20/2014	N/A	NDA	237 mL in 1 BOTTLE, PLASTIC (0116-0237-01)	Decreased Cell Wall Integrity [PE]
Antiseptic Skin Cleanser	0116-0401-50	4 mg/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0401	Chlorhexidine Gluconate 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	11/01/2013	02/28/2027	NDA	237 mL in 1 BOTTLE, PLASTIC (0116-0401-50)	Decreased Cell Wall Integrity [PE]
ANTISEPTIC SKIN CLEANSER	0116-0407-01	4 g/100mL	SOLUTION	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0407	CHLORHEXIDINE GLUCONATE	CHLORHEXIDINE GLUCONATE	HUMAN PRESCRIPTION DRUG	01/01/2012	N/A	NDA	237 mL in 1 BOTTLE, PLASTIC (0116-0407-01)	Decreased Cell Wall Integrity [PE]
Antiseptic Skin Cleanser	0116-0767-08	4 g/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0767	CHLORHEXIDINE GLUCONATE 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	08/31/2011	N/A	NDA	237 mL in 1 BOTTLE (0116-0767-08)	Decreased Cell Wall Integrity [PE]
Antiseptic Skin Cleanser	0116-0767-16	4 g/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0767	CHLORHEXIDINE GLUCONATE 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	01/01/2017	N/A	NDA	473 mL in 1 BOTTLE (0116-0767-16)	Decreased Cell Wall Integrity [PE]
Antiseptic Skin Cleanser	0116-0767-18	4 g/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0767	CHLORHEXIDINE GLUCONATE 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	11/14/2022	01/31/2027	NDA	532 mL in 1 BOTTLE, PUMP (0116-0767-18)	Decreased Cell Wall Integrity [PE]
ANTISEPTIC SKIN CLEANSER	0116-1061-01	4 g/100mL	SOLUTION	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-1061	CHLORHEXIDINE GLUCONATE	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	08/31/2011	N/A	NDA	15142 mL in 1 JUG (0116-1061-01)	Decreased Cell Wall Integrity [PE]
ANTISEPTIC SKIN CLEANSER	0116-1061-08	4 g/100mL	SOLUTION	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-1061	CHLORHEXIDINE GLUCONATE	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	08/31/2011	N/A	NDA	237 mL in 1 BOTTLE, PLASTIC (0116-1061-08)	Decreased Cell Wall Integrity [PE]
ANTISEPTIC SKIN CLEANSER	0116-1061-16	4 g/100mL	SOLUTION	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-1061	CHLORHEXIDINE GLUCONATE	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	08/31/2011	N/A	NDA	437 mL in 1 BOTTLE, PLASTIC (0116-1061-16)	Decreased Cell Wall Integrity [PE]
ANTISEPTIC SKIN CLEANSER	0116-1061-18	4 g/100mL	SOLUTION	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-1061	CHLORHEXIDINE GLUCONATE	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	08/31/2011	08/31/2026	NDA	592 mL in 1 BOTTLE (0116-1061-18)	Decreased Cell Wall Integrity [PE]
ANTISEPTIC SKIN CLEANSER	0116-1061-32	4 g/100mL	SOLUTION	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-1061	CHLORHEXIDINE GLUCONATE	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	08/31/2011	N/A	NDA	946 mL in 1 BOTTLE, PLASTIC (0116-1061-32)	Decreased Cell Wall Integrity [PE]
ANTISEPTIC SKIN CLEANSER	0116-1061-40	4 g/100mL	SOLUTION	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-1061	CHLORHEXIDINE GLUCONATE	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	01/01/2019	N/A	NDA	118 mL in 1 BOTTLE (0116-1061-40)	Decreased Cell Wall Integrity [PE]
ANTISEPTIC SKIN CLEANSER	0116-1061-04	4 g/100mL	SOLUTION	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-1061	Chlorhexidine Gluconate	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	08/31/2011	N/A	NDA	118 mL in 1 BOTTLE, PLASTIC (0116-1061-04)	Decreased Cell Wall Integrity [PE]
ANTISEPTIC SKIN CLEANSER	0116-1061-15	4 g/100mL	SOLUTION	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-1061	Chlorhexidine Gluconate	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	08/01/2018	N/A	NDA	15 mL in 1 CARTON (0116-1061-15)	Decreased Cell Wall Integrity [PE]
Antiseptic Skin Cleanser	0116-3678-07	4 mg/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-3678	Chlorhexidine Gluconate 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	01/01/2019	11/30/2026	NDA	473 mL in 1 BOTTLE (0116-3678-07)	Decreased Cell Wall Integrity [PE]

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
Antiseptic Skin Cleanser	0116-3678-08	4 mg/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-3678	Chlorhexidine Gluconate 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	01/01/2013	11/30/2026	NDA	237 mL in 1 BOTTLE, PLASTIC (0116-3678-08)	Decreased Cell Wall Integrity [PE]
Antiseptic Skin Cleanser	11822-0116-5	4 g/100mL	LIQUID	TOPICAL	NDA019125	Rite Aid	11822-0116	Chlorhexidine Gluconate 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	03/25/2021	N/A	NDA	237 mL in 1 BOTTLE (11822-0116-5)	Decreased Cell Wall Integrity [PE]
Bactoshield CHG	0116-0038-03	2 mg/100mL	SOLUTION	TOPICAL	NDA019422	Xttrium Laboratories, Inc.	0116-0038	Chlorhexidine Gluconate 2%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	11/16/2022	01/31/2027	NDA	118 mL in 1 BOTTLE (0116-0038-03)	Decreased Cell Wall Integrity [PE]
Bactoshield CHG	0116-0039-03	2 mg/100mL	SOLUTION	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0039	Chlorhexidine Gluconate 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	11/21/2022	N/A	NDA	118 mL in 1 BOTTLE (0116-0039-03)	Decreased Cell Wall Integrity [PE]
Bactoshield CHG	0116-0039-24	2 mg/100mL	SOLUTION	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0039	Chlorhexidine Gluconate 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	11/22/2022	11/30/2027	NDA	946 mL in 1 BOTTLE (0116-0039-24)	Decreased Cell Wall Integrity [PE]
BD E-Z Scrub	0116-0505-01	40 g/1000mL	SOLUTION	TOPICAL	NDA019127	Xttrium Laboratories, Inc.	0116-0505	chlorhexidine gluconate	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	01/01/2006	N/A	NDA	946 mL in 1 BOTTLE (0116-0505-01)	Decreased Cell Wall Integrity [PE]
BD E-Z Scrub	0116-0505-02	40 g/1000mL	SOLUTION	TOPICAL	NDA019127	Xttrium Laboratories, Inc.	0116-0505	chlorhexidine gluconate	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	01/01/2006	N/A	NDA	946 mL in 1 BOTTLE (0116-0505-02)	Decreased Cell Wall Integrity [PE]
BD E-Z Scrub	0116-0506-02	20 mg/mL	SOLUTION	TOPICAL	NDA019422	Xttrium Laboratories, Inc.	0116-0506	chlorhexidine gluconate	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	04/01/2001	N/A	NDA	946 mL in 1 BOTTLE (0116-0506-02)	Decreased Cell Wall Integrity [PE]
BETASEPT	0116-0200-01	.04 mg/mL	SOLUTION	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0200	Antiseptic Surgical Scrub	CHLORHEXIDINE GLUCONATE	HUMAN PRESCRIPTION DRUG	06/01/1993	N/A	NDA	3785 mL in 1 BOTTLE (0116-0200-01)	Decreased Cell Wall Integrity [PE]
BETASEPT	0116-0200-04	.04 mg/mL	SOLUTION	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0200	Antiseptic Surgical Scrub	CHLORHEXIDINE GLUCONATE	HUMAN PRESCRIPTION DRUG	06/01/1993	N/A	NDA	118 mL in 1 BOTTLE (0116-0200-04)	Decreased Cell Wall Integrity [PE]
BETASEPT	0116-0200-08	.04 mg/mL	SOLUTION	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0200	Antiseptic Surgical Scrub	CHLORHEXIDINE GLUCONATE	HUMAN PRESCRIPTION DRUG	06/01/1993	N/A	NDA	237 mL in 1 BOTTLE (0116-0200-08)	Decreased Cell Wall Integrity [PE]
BETASEPT	0116-0200-16	.04 mg/mL	SOLUTION	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0200	Antiseptic Surgical Scrub	CHLORHEXIDINE GLUCONATE	HUMAN PRESCRIPTION DRUG	06/01/1993	N/A	NDA	473 mL in 1 BOTTLE (0116-0200-16)	Decreased Cell Wall Integrity [PE]
BETASEPT	0116-0200-30	.04 mg/mL	SOLUTION	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0200	Antiseptic Surgical Scrub	CHLORHEXIDINE GLUCONATE	HUMAN PRESCRIPTION DRUG	06/01/1993	N/A	NDA	946 mL in 1 BOTTLE (0116-0200-30)	Decreased Cell Wall Integrity [PE]
BETASEPT	0116-0200-32	.04 mg/mL	SOLUTION	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0200	Antiseptic Surgical Scrub	CHLORHEXIDINE GLUCONATE	HUMAN PRESCRIPTION DRUG	06/01/1993	N/A	NDA	946 mL in 1 BOTTLE (0116-0200-32)	Decreased Cell Wall Integrity [PE]
Calcarea Oxalica	37662-0116-1	1 [hp_Q]/1	PELLET	ORAL		Hahnemann Laboratories, INC.	37662-0116	Calcarea Oxalica	CALCIUM OXALATE MONOHYDRATE	HUMAN OTC DRUG	05/19/2022	N/A	UNAPPROVED HOMEOPATHIC	10000 PELLET in 1 BOTTLE, GLASS (37662-0116-1)	Blood Coagulation Factor [EPC], Calcium [CS], Cations, Divalent [CS], Increased Coagulation Factor Activity [PE]
Cardinal Health	0116-0061-04	4 g/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0061	CHLORHEXIDINE GLUCONATE 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	07/24/2015	N/A	NDA	118 mL in 1 BOTTLE, PLASTIC (0116-0061-04)	Decreased Cell Wall Integrity [PE]

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class
Cardinal Health	0116-0061-08	4 g/100mL	LIQUID	TOPICAL	NDA019125	Xttrium Laboratories, Inc.	0116-0061	CHLORHEXIDINE GLUCONATE 4%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	07/24/2015	02/28/2027	NDA	237 mL in 1 BOTTLE, PLASTIC (0116-0061-08)	Decreased Cell Wall Integrity [PE]
Cardinal Health Antiseptic Skin Cleanser	0116-0113-04	2 g/100mL	SOLUTION	TOPICAL	NDA019422	Xttrium Laboratories, Inc.	0116-0113	CHLORHEXIDINE GLUCONATE 2%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	05/01/2015	N/A	NDA	118 mL in 1 BOTTLE, PLASTIC (0116-0113-04)	Decreased Cell Wall Integrity [PE]
Cardinal Health Antiseptic Skin Cleanser	0116-0113-08	2 g/100mL	SOLUTION	TOPICAL	NDA019422	Xttrium Laboratories, Inc.	0116-0113	CHLORHEXIDINE GLUCONATE 2%	CHLORHEXIDINE GLUCONATE	HUMAN OTC DRUG	05/01/2015	N/A	NDA	237 mL in 1 BOTTLE, PLASTIC (0116-0113-08)	Decreased Cell Wall Integrity [PE]
Chlorhexidine Gluconate	0116-0101-01	12 mg/mL	LIQUID	ORAL	ANDA077789	Xttrium Laboratories, Inc.	0116-0101	Chlorhexidine Gluconate	CHLORHEXIDINE GLUCONATE	HUMAN PRESCRIPTION DRUG	06/30/2017	N/A	ANDA	473 mL in 1 BOTTLE (0116-0101-01)	Decreased Cell Wall Integrity [PE]
Chlorhexidine Gluconate	0116-0101-04	12 mg/mL	LIQUID	ORAL	ANDA077789	Xttrium Laboratories, Inc.	0116-0101	Chlorhexidine Gluconate	CHLORHEXIDINE GLUCONATE	HUMAN PRESCRIPTION DRUG	01/22/2016	N/A	ANDA	118 mL in 1 BOTTLE, PLASTIC (0116-0101-04)	Decreased Cell Wall Integrity [PE]
Chlorhexidine Gluconate	0116-0175-16	1.2 mg/mL	RINSE	ORAL	ANDA077789	Xttrium Laboratories, Inc.	0116-0175	Chlorhexidine Gluconate	CHLORHEXIDINE GLUCONATE	HUMAN PRESCRIPTION DRUG	06/18/2009	N/A	ANDA	473 mL in 1 BOTTLE, PLASTIC (0116-0175-16)	Decreased Cell Wall Integrity [PE]

Showing 1 to 50 of 126 entries

Previous 1 2 3 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: **DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)**

See also: **Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)**
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Company Particulars

Xttrium Laboratories, Inc.

Corporate Address: 1400 East Business Center Drive, Mount Prospect, IL 60056 USA
FEIN: 36-2030325
www.xttrium.com

Drug Labeler Code: 0116
Incorporation State: DE
Incorporation Date: 8/5/1939

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
GIL	3400 West Lake Avenue Glenview, IL 60026 County: Cook	N/A	N/A - No CS	119543594	No	(773) 268-5800	(847) 635-9825

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Madeleine Creevy McNally	1400 East Business Center Drive Mount Prospect, IL 60056	Co-President		[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Madeleine Creevy McNally	1400 East Business Center Drive Mount Prospect, IL 60056	Co-President	7.8		[redacted]		
Kevin Lucas Creevy	1200 East Business Center Drive Mount Prospect, IL 60056	Co-President	7.8	No			
Michael K Creevy	[redacted]	Vice President Sales & Marketing	7.8				
Kathleen Creevy Enright			7.8				
Meghan A Greene			7.8				
Creevy Dynasty Trust		N/A	31.30	N/A	[redacted]	N/A	N/A
Margaret J. Grady Gift Trust	1400 East Business Center Drive Mount Prospect, IL 60056	N/A	5.06	N/A		N/A	N/A
Mary Catherine Creevy O'Connor Xttrium Trust	1400 East Business Center Drive Mount Prospect, IL 60056	N/A	4.05	N/A		N/A	N/A
Catherine O'Connor LaCross Gift Trust	1400 East Business Center Drive Mount Prospect, IL 60056	N/A	5.06	N/A		N/A	N/A
William G. O'Connor Gift Trust	1400 East Business Center Drive Mount Prospect, IL 60056	N/A	5.06	N/A		N/A	N/A
Matthew F. O'Connor Gift Trust	1400 East Business Center Drive Mount Prospect, IL 60056	N/A	5.06	N/A		N/A	N/A

Company Particulars

Kevin S. Creevy Trust	1400 East Business Center Drive Mount Prospect, IL 60056	N/A	5.41	N/A	use Kevin S. Social-see notes	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Madeleine Creevy McNally	1400 East Business Center Drive Mount Prospect, IL 60056	Co-President		[redacted]		
Kevin Lucas Creevy	1200 East Business Center Drive Mount Prospect, IL 60056	Co-President	No			
Kevin S. Creevy	[redacted]	Chairman	No			

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
Incorp Services, Inc.			

Disciplinary History: AL 2009, MO 2010, RI 2011, UT 2025, MD 2026

Org Chart

XTTRIUM
xl
LABORATORIES
INNOVATIONS IN PRODUCTS AND SYSTEMS

Xttrium Laboratories, Inc. Ownership Chart

Creevy Dynasty Trust - 31.30% (DRE with Kevin S. Creevy as grantor of the trust SSN: [redacted]
Madeleine Creevy McNally - 7.8% (SSN [redacted]
Michael K. Creevy - 7.8% (SSN: [redacted]
Kevin L. Creevy - 7.8% (SSN: [redacted]
Kathleen Creevy Enright - 7.8% [redacted]
Meghan A. Greene - 7.8% (SSN [redacted]
Kevin S. Creevy Trust - 5.41% (DRE with Kevin S. Creevy as grantor of the trust SSN: [redacted]
Catherine O'Connor LaCross Gift Trust - 5.06% FEIN: [redacted]
Margaret J. Grady Gift Trust - 5.06% FEIN: [redacted]
Matthew F. O'Connor Gift Trust - 5.06% FE [redacted]
William G. O'Connor Gift Trust - 5.06% FEI [redacted]
Mary Catherine Creevy O'Connor Xttrium Trust - 4.05% FEIN: [redacted]



100%

Xttrium Laboratories, Inc.
FEIN:36-2030325

Good Standing DE

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "XTTRIUM LABORATORIES, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SIXTH DAY OF AUGUST, A.D. 2025.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

371318 8300

SR# 20253584445

Authentication: 204405799

Date: 08-06-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

Verification of Home State License (IL)

Illinois Department of Financial and Professional Regulation

Lookup Detail View

Contact

Contact Information

Name	City/State/Zip	DBA / AKA
Xttrium Laboratories, Inc.	Glenview, IL 60026	•

License

License Information

License Number	Description	Status	First Effective Date	Effective Date	Expiration Date	Ever Disciplined
004005708	LICENSED WHOLESALE DRUG DISTRIBUTOR	ACTIVE	11/20/2025	11/20/2025	12/31/2026	N

Other Licenses

Other Licenses

License Number	Description	Status	First Effective Date	Effective Date	Expiration Date	Ever Disciplined
004001871	LICENSED WHOLESALE DRUG DISTRIBUTOR	CLOSED	12/23/2003	10/13/2010	12/31/2012	N
004003024	LICENSED WHOLESALE DRUG DISTRIBUTOR	CHANGE OF OWNERSHIP	05/03/2010	10/10/2024	12/31/2026	N
004004966	LICENSED WHOLESALE DRUG DISTRIBUTOR	CHANGE OF OWNERSHIP	08/17/2021	10/10/2024	12/31/2026	N
004005706	LICENSED WHOLESALE DRUG DISTRIBUTOR	ACTIVE	12/02/2025	12/02/2025	12/31/2026	N
004005707	LICENSED WHOLESALE DRUG DISTRIBUTOR	ACTIVE	02/14/2026	02/14/2026	12/31/2026	N

Generated on: 3/3/2026 10:18:42 AM

Home State Permit

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
004.005708

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
12/31/2026

LICENSED WHOLESALE DRUG DISTRIBUTOR

WHOLESALE DRUG

XTTRIUM LABORATORIES, INC.
MADELEINE CREEVY MCNALLY
3400 W LAKE AVE
GLENVIEW, IL 60026-8065

MARIO TRETO, JR.
SECRETARY

CAMILE LINDSAY
DIRECTOR

The official status of this license can be verified at IDFPR.illinois.gov

20649562

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 304239

GENERAL PURPOSE RIDER

To be attached to and form part of Bond Number 9171724 effective June 19, 2015
issued by the Swiss Re Corporate Solutions Premier Insurance Corporation
in the amount of One Hundred Thousand Dollars and No Cents $100,000.00 DOLLARS,
on behalf of Xttrium Laboratories, Inc.
as Principal and in favor of Nevada State Board of Pharmacy
as Obligee:

Now, Therefore, it is agreed that:

Two Locations are covered under this bond: 1200 E Business Center Drive Mount Prospect, Il. 60056 & 3400 West Lake Avenue Mount Prospect, Il. 60056

It is further understood and agreed that all other terms and conditions of this bond shall remain unchanged.

This rider is to be effective the 18th day of July, 2025.

Signed, sealed and dated this 15th day of August, 2025.

Xttrium Laboratories, Inc.
(Principal)

By: Vijay Verma

Swiss Re Corporate Solutions Premier Insurance Corporation
(Surety)

By: William Reidinger
Attorney-in-Fact

SEAL

Accepted By:

VIJAY VERMA

SWISS RE CORPORATE SOLUTIONS

SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION ("SRCSAIC")
SWISS RE CORPORATE SOLUTIONS PREMIER INSURANCE CORPORATION ("SRCSPIC")

GENERAL POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, THAT SRCSAIC, a corporation duly organized and existing under laws of the State of Missouri, and having its principal office in the City of Kansas City, Missouri, and SRCSPIC, a corporation organized and existing under the laws of the State of Missouri and having its principal office in the City of Kansas City, Missouri, each does hereby make, constitute, and appoint: **William Reidinger**

Principal: Xttrium Laboratories, Inc.
Obligee: Nevada State Board of Pharmacy
Bond Description: Pharmaceutical Wholesaler Surety Bond
Bond Number: 9171724
Bond Amount: See Bond Form

Its true and lawful Attorney(s)-In-Fact, to make, execute, seal and deliver, for and on its behalf and as its act and deed, bonds or other writings obligatory in the nature of a bond on behalf of each of said Companies, as surety, on contracts of suretyship as are or may be required or permitted by law, regulation, contract or otherwise, provided that no bond or undertaking or contract or suretyship executed under this authority shall exceed the amount of:

FIFTY MILLION ($50,000,000.00) DOLLARS

This Power of Attorney is granted and is signed by facsimile under and by the authority of the following Resolutions adopted by the Boards of Directors of both SRCSAIC and SRCSPIC at meetings duly called and held on the 9th of May 2012:

"RESOLVED, that any two of the President, any Managing Director, any Senior Vice President, any Vice President, the Secretary or any Assistant Secretary be, and each or any of them hereby is, authorized to execute a Power of Attorney qualifying the attorney named in the given Power of Attorney to execute on behalf of the Corporation bonds, undertakings and all contracts of surety, and that each or any of them hereby is authorized to attest to the execution of any such Power of Attorney and to attach therein the seal of the Corporation; and it is

FURTHER RESOLVED, that the signature of such officers and the seal of the Corporation may be affixed to any such Power of Attorney or to any certificate relating thereto by facsimile, and any such Power of Attorney or certificate bearing such facsimile signatures or facsimile seal shall be binding upon the Corporation when so affixed and in the future with regard to any bond, undertaking or contract of surety to which it is attached."

SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION CORPORATE SEAL 1973 MISSOURI

SWISS RE CORPORATE SOLUTIONS PREMIER INSURANCE CORPORATION CORPORATE SEAL MISSOURI

By _____
Erik Janssens, Senior Vice President of SRCSAIC & Senior Vice President of SRCSPIC

By _____
Gerald Jagrowski, Vice President of SRCSAIC & Vice President of SRCSPIC

IN WITNESS WHEREOF, SRCSAIC and SRCSPIC have caused their official seals to be hereunto affixed, and these presents to be signed by their authorized officers this 10TH day of NOVEMBER, 20 22

Swiss Re Corporate Solutions America Insurance Corporation
Swiss Re Corporate Solutions Premier Insurance Corporation

State of Illinois
County of Cook ss

On this 10TH day of NOVEMBER, 20 22, before me, a Notary Public personally appeared Erik Janssens, Senior Vice President of SRCSAIC and Senior Vice President of SRCSPIC and Gerald Jagrowski, Vice President of SRCSAIC and Vice President of SPCSPIC, personally known to me, who being by me duly sworn, acknowledged that they signed the above Power of Attorney as officers of and acknowledged said instrument to be the voluntary act and deed of their respective companies.

OFFICIAL SEAL
CHRISTINA MANISCO
NOTARY PUBLIC, STATE OF ILLINOIS
My Commission Expires March 28, 2026

Christina Manisco
Christina Manisco, Notary

I, Jeffrey Goldberg, the duly elected Senior Vice President and Assistant Secretary of SRCSAIC and SRCSPIC, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney given by said SRCSAIC and SRCSPIC, which is still in full force and effect.
IN WITNESS WHEREOF, I have set my hand and affixed the seals of the Companies this 15th day of August, 2025.

Jeffrey Goldberg, Senior Vice President &
Assistant Secretary of SRCSAIC and
SRCSPIC

GENERAL SURETY RIDER

To be attached and form a part of

Bond No.	9171724
For	Pharmaceutical Wholesaler Surety Bond
Dated effective	06/19/2015 (MONTH, DAY, YEAR)
Executed by	Xttrium Laboratories, Inc., as Principal, (PRINCIPAL)
And by	Swiss Re Corporate Solutions Premier Insurance Corporation, as Surety, (SURETY)
And in favor of	Nevada State Board of Pharmacy (OBLIGEE)

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

INFORMATION	FROM	TO
Principal Address	3400 West Lake Avenue	3400 West Lake Avenue
Principal City	Mount Prospect	Glenview
Principal Zip	60056	60056

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective 07/18/2025
(MONTH, DAY, YEAR)

Signed and Sealed 03/26/2026
(MONTH, DAY, YEAR)

SEAL

Xttrium Laboratories, Inc.
PRINCIPAL

BY Vijay Verma CFO
TITLE

Swiss Re Corporate Solutions Premier Insurance Corporation
SURETY

BY
William Reidinger, ATTORNEY-IN-FACT

SWISS RE CORPORATE SOLUTIONS

SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION ("SRCSAIC")
SWISS RE CORPORATE SOLUTIONS PREMIER INSURANCE CORPORATION ("SRCSPIC")

GENERAL POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, THAT SRCSAIC, a corporation duly organized and existing under laws of the State of Missouri, and having its principal office in the City of Kansas City, Missouri, and SRCSPIC, a corporation organized and existing under the laws of the State of Missouri and having its principal office in the City of Kansas City, Missouri, each does hereby make, constitute, and appoint: **William Reidinger**

Principal: Xttrium Laboratories, Inc.
Obligee: Nevada State Board of Pharmacy
Bond Description: Pharmaceutical Wholesaler Surety Bond
Bond Number: 9171724
Bond Amount: See Bond Form

Its true and lawful Attorney(s)-in-Fact, to make, execute, seal and deliver, for and on its behalf and as its act and deed, bonds or other writings obligatory in the nature of a bond on behalf of each of said Companies, as surety, on contracts of suretyship as are or may be required or permitted by law, regulation, contract or otherwise, provided that no bond or undertaking or contract or suretyship executed under this authority shall exceed the amount of:

FIFTY MILLION ($50,000,000.00) DOLLARS

This Power of Attorney is granted and is signed by facsimile under and by the authority of the following Resolutions adopted by the Boards of Directors of both SRCSAIC and SRCSPIC at meetings duly called and held on the 9th of May 2012:

"RESOLVED, that any two of the President, any Managing Director, any Senior Vice President, any Vice President, the Secretary or any Assistant Secretary be, and each or any of them hereby is, authorized to execute a Power of Attorney qualifying the attorney named in the given Power of Attorney to execute on behalf of the Corporation bonds, undertakings and all contracts of surety, and that each or any of them hereby is authorized to attest to the execution of any such Power of Attorney and to attach therein the seal of the Corporation; and it is

FURTHER RESOLVED, that the signature of such officers and the seal of the Corporation may be affixed to any such Power of Attorney or to any certificate relating thereto by facsimile, and any such Power of Attorney or certificate bearing such facsimile signatures or facsimile seal shall be binding upon the Corporation when so affixed and in the future with regard to any bond, undertaking or contract of surety to which it is attached."

SWISS RE CORPORATE SOLUTIONS AMERICA INSURANCE CORPORATION CORPORATE SEAL 1973 MISSOURI

SWISS RE CORPORATE SOLUTIONS PREMIER INSURANCE CORPORATION CORPORATE SEAL MISSOURI

By _____
Erik Janssens, Senior Vice President of SRCSAIC & Senior Vice President of SRCSPIC

By _____
Gerald Jagrowski, Vice President of SRCSAIC & Vice President of SRCSPIC

IN WITNESS WHEREOF, SRCSAIC and SRCSPIC have caused their official seals to be hereunto affixed, and these presents to be signed by their authorized officers this 10TH day of NOVEMBER, 20 22

Swiss Re Corporate Solutions America Insurance Corporation
Swiss Re Corporate Solutions Premier Insurance Corporation

State of Illinois
County of Cook ss

On this 10TH day of NOVEMBER, 20 22, before me, a Notary Public personally appeared Erik Janssens, Senior Vice President of SRCSAIC and Senior Vice President of SRCSPIC and Gerald Jagrowski, Vice President of SRCSAIC and Vice President of SPCSPIC, personally known to me, who being by me duly sworn, acknowledged that they signed the above Power of Attorney as officers of and acknowledged said instrument to be the voluntary act and deed of their respective companies.

OFFICIAL SEAL
CHRISTINA MANISCO
NOTARY PUBLIC, STATE OF ILLINOIS
My Commission Expires March 28, 2026

Christina Manisco
Christina Manisco, Notary

I, Jeffrey Goldberg, the duly elected Senior Vice President and Assistant Secretary of SRCSAIC and SRCSPIC, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney given by said SRCSAIC and SRCSPIC, which is still in full force and effect.
IN WITNESS WHEREOF, I have set my hand and affixed the seals of the Companies this 26th day of March, 2026.

Jeffrey Goldberg, Senior Vice President &
Assistant Secretary of SRCSAIC and
SRCSPIC

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 9171724

Application/License No. _____

Xttrium Laboratories, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1200 E. Business Center St., Mount Prospect, IL 60056 (Address of Applicant/Principal), as PRINCIPAL, and Washington International Insurance Company (Surety Company), a corporation organized under the laws of the state of NH (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 475 North Martingale Road, Suite 850, Schaumurg, IL 60173 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 07/17/2015 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 19th day of June, 20 15.

APPLICANT/PRINCIPAL
Xttrium Laboratories, Inc.

Authorized Representative

SURETY COMPANY
Washington International Insurance Company

Surety Company's Representative

William Reidinger, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Donna M. Tyler

Witness

Countersigned by:

Nevada Resident Agent William Reidinger

BOND FROM
INS. CO. FOR
NEVADA Medical

WILLIAM PATRICK REIDINGER
C/O ASSURANCE AGENCY LTD
1750 E GOLF RD FL 11
SCHAUMBURG IL 60173-5835

Scott Kipper, Commissioner of Insurance

WILLIAM PATRICK REIDINGER

License Number 163038

is licensed to engage in the business of insurance in the State of Nevada in the capacity stated below, subject to applicable laws and regulations.

		Effective Date:	Expiration Date:
License Type:	Non-Resident Producer	06-13-2002	07-01-2017
Qualifications:	Casualty, Property, Surety		

Licensees must notify the Division of any change of address within 30 days of the change. You are subject to revocation for noncompliance.
Individuals – If you are affiliated to a business entity it will not print on the license. Individuals must be properly affiliated to the business entity's license prior to transacting insurance on the entity's behalf. The individual and the business entity are responsible for maintaining the affiliation.

A producer of insurance acting as an agent of the insurer must be appointed by the insurer prior to transacting insurance.

This license must be conspicuously displayed in your place of business that is open to the public.

WILLIAM PATRICK REIDINGER

License Number 163038
National Producer ID 2129248

is licensed to engage in the business of insurance in the State of Nevada in the capacity stated below, subject to applicable laws and regulations.

LICENSE TYPE	EFFECTIVE DATE
Non-Resident Producer	06-13-2002
QUALIFICATIONS	**EXPIRATION DATE**
Casualty, Property, Surety	07-01-2017

Scott J. Kipper, Commissioner of Insurance

Non-Resident Producer Firm

Casualty , Health , Life , Property

ASSURANCE AGENCY LTD
ONE CENTURY CENTER
1750 E GOLF RD
SCHAUMBURG , IL 60173

is authorized to transact business as described above

License No: 9680 Issue Date: 10-01-2001 Expiration Date: 02-01-2016

Generated by Sircon 76927754

Nevada Division of Insurance

THIS IS TO CERTIFY THAT

ASSURANCE AGENCY LTD
ONE CENTURY CENTER , 1750 E GOLF RD ,
SCHAUMBURG , IL 60173

LICENSE NUMBER: 9680

IS HEREBY AUTHORIZED TO TRANSACT BUSINESS IN ACCORDANCE TO THE LICENSE DESCRIPTION SHOWN BELOW:

Non-Resident Producer Firm
Casualty , Health , Life , Property

Issue Date: 10-01-2001 Expiration Date: 02-01-2016

Generated by Sircon 76927754

NAS SURETY GROUP

NORTH AMERICAN SPECIALTY INSURANCE COMPANY
WASHINGTON INTERNATIONAL INSURANCE COMPANY

GENERAL POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, THAT North American Specialty Insurance Company, a corporation duly organized and existing under laws of the State of New Hampshire, and having its principal office in the City of Manchester, New Hampshire, and Washington International Insurance Company, a corporation organized and existing under the laws of the State of New Hampshire and having its principal office in the City of Schaumburg, Illinois, each does hereby make, constitute and appoint:

WILLIAM REIDINGER, DONNA WRIGHT, DONNA M. TYLER, HINA AZAM,

KAREN E. BOGARD, JOSEPH HALLERAN, MATTHEW V. BUOL and REBECCA R. ALVES

JOINTLY OR SEVERALLY

Its true and lawful Attorney(s)-in-Fact, to make, execute, seal and deliver, for and on its behalf and as its act and deed, bonds or other writings obligatory in the nature of a bond on behalf of each of said Companies, as surety, on contracts of suretyship as are or may be required or permitted by law, regulation, contract or otherwise, provided that no bond or undertaking or contract or suretyship executed under this authority shall exceed the amount of:

TEN MILLION ($10,000,000.00) DOLLARS

This Power of Attorney is granted and is signed by facsimile under and by the authority of the following Resolutions adopted by the Boards of Directors of both North American Specialty Insurance Company and Washington International Insurance Company at meetings duly called and held on the 9th of May, 2012:

"RESOLVED, that any two of the Presidents, any Managing Director, any Senior Vice President, any Vice President, any Assistant Vice President, the Secretary or any Assistant Secretary be, and each or any of them hereby is authorized to execute a Power of Attorney qualifying the attorney named in the given Power of Attorney to execute on behalf of the Company bonds, undertakings and all contracts of surety, and that each or any of them hereby is authorized to attest to the execution of any such Power of Attorney and to attach therein the seal of the Company; and it is

FURTHER RESOLVED, that the signature of such officers and the seal of the Company may be affixed to any such Power of Attorney or to any certificate relating thereto by facsimile, and any such Power of Attorney or certificate bearing such facsimile signatures or facsimile seal shall be binding upon the Company when so affixed and in the future with regard to any bond, undertaking or contract of surety to which it is attached."

NORTH AMERICAN SPECIALTY INSURANCE COMPANY CORPORATE SEAL 1973 NEW HAMPSHIRE

By _____
Steven P. Anderson, Senior Vice President of Washington International Insurance Company & Senior Vice President of North American Specialty Insurance Company

By _____
David M. Layman, Vice President of Washington International Insurance Company & Vice President of North American Specialty Insurance Company

WASHINGTON INTERNATIONAL INSURANCE COMPANY CORPORATE SEAL NEW HAMPSHIRE

IN WITNESS WHEREOF, North American Specialty Insurance Company and Washington International Insnrance Company have caused their official seals to be hereunto affixed, and these presents to be signed by their authorized officers this 27th day of February, 2013.

North American Specialty Insurance Company
Washington International Insurance Company

State of Illinois
County of Cook ss:

On this 27th day of February, 2013, before me, a Notary Public personally appeared Steven P. Anderson, Senior Vice President of Washington International Insurance Company and Senior Vice President of North American Specialty Insurance Company and David M. Layman, Vice President of Washington International Insurance Company and Vice President of North American Specialty Insurance Company, personally known to me, who being by me duly sworn, acknowledged that they signed the above Power of Attorney as officers of and acknowledged said instrument to be the voluntary act and deed of their respective companies.

"OFFICIAL SEAL"
DONNA D. SKLENS
Notary Public, State of Illinois
My Commission Expires 10/06/2015

Donna D. Sklens
Donna D. Sklens, Notary Public

I, Jeffrey Goldberg, the duly elected Assistant Secretary of North American Specialty Insurance Company and Washington International Insurance Company, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney given by said North American Specialty Insurance Company and Washington International Insurance Company, which is still in full force and effect.

IN WITNESS WHEREOF, I have set my hand and affixed the seals of the Companies this 19th day of June, 20 15

Jeffrey Goldberg, Vice President & Assistant Secretary of
Washington International Insurance Company & North American Specialty Insurance Company

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Xttrium Laboratories, Inc.

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 3400 West Lake Avenue

City: Glenview State: IL Zip: 60026

Mailing Address (if different from physical address): c/o State License Servicing, Inc. 225 Dolson Avenue, 4th Floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: www.xttrium.com

Licensing Company Email: XLI@slsny.com

Section 2: Personal Information

First: Madeleine Middle: Creevy Last: McNally

Alias(es, nicknames, name changes, etc.): Madeleine Marie Creevy

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: Wilmette State: IL Zip: [redacted]

Telephone: [redacted] Email: mcreevy@xttrium.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	Address	City	State	Zip	From - To (MM/YY – MM/YY)	Diploma/Degree obtained, if any
University of Montana		Missoula	MT		2000 - 2005	Bachelors Degree
Loyola Academy	1100 Laramie Ave	Wilmette	IL	60091	1996 - 1999	High School Diploma

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2020 - Current	[redacted]	Wilmette	IL	[redacted]
2017 - 2019		Chicago	IL	
2015 - 2016		Winnetka	IL	

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Xttrium Laboratories, Inc.				From - To (MM/YY – MM/YY): 2025 - Present
Business Address: 3400 West Lake Avenue		City: Glenview	State: IL	Zip: 60026
Phone: (773) 268-5800	Title: Co-President			Number of Employed Hours: ~ 2,360 hours
Description of Duties: Day-to-day manager of commercial business with VP, All director level roles report into EVP and VP, Ensures product integrity, Coordinates logistics, Maintain Records, Oversees receiving, storage and distribution of products, Supervises inventory and customer service.				

Business Name: Xttrium Laboratories Inc.				From - To (MM/YY – MM/YY): 2012 - 2025
Business Address: 1200 E. Business Center Drive		City: Mount Prospect	State: IL	Zip: 60056
Phone: (773) 268-5800	Title: Executive Vice President			Number of Employed Hours: ~ 27,040 hours
Description of Duties: Day-to-day manager of commercial business with VP, All director level roles report into EVP and VP, Ensures product integrity, Coordinates logistics, Maintain Records, Oversees receiving, storage and distribution of products, Supervises inventory and customer service.				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	✓	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 & 2 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
2/18/2000		ID		Shoshone
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
CR-2000-0032465		State of Idaho		
Reason/Charge				
Possession of marijuana				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Madeleine Creevy McNally				
Name of Business/Industry/Entity				

Provide explanation below:

*Please see attached discipline summary

Madeleine Creevy McNally

Original Signature (electronic, copies or stamps not accepted)

2/24/2026

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

*Please see attached discipline summary

Original Signature (electronic, copies or stamps not accepted)

2/24/2026
Date

Personal Discipline

6/12/2025

To Whom It May Concern:

My name is Madeleine Creevy McNally. I am part of the ownership group at Xttrium Labs. Unfortunately, I was arrested and charged with possession of marijuana while attending the University of Montana.

I plead guilty and paid a $100 fine along with court fees. I have attached the court disposition records for your review. I sincerely regret what happened.

Thanks,

Madeleine Creevy McNally

Madeleine Creevy McNally

First Judicial District Court - Shoshone County
Complete Case History
CR-2000-0032465

User: DEBI

State of Idaho vs. Madeline M Creevy

Filed: 2/22/2000
Subtype: Misdemeanor

Physical File: Y Appealed: N

Comment:

Defendant

Name: Creevy, Madeline M
Address: [redacted]
Missoula MT [redacted]
Phone Number: Work:
Driver's license: [redacted] MT
Employer:
Comment:

SSN: [redacted]
DOB:
Sex:
FPC Number:

Money Due Date: 6/13/2000 Extension Date: Hold Date:
Agreement Date: Terms:
Trial Held: No Trial
First Appearance: 8/29/2000

Bonds

Cash

Amount: 360.00 Date: 2/23/2000 Received: 360.00 Write off: Balance: 0.00
Other party: Ryan Arnold [redacted]
Exonerated: 6/13/2000

Exonerated:	6/13/2000	Number: 40504	196.50	
		Total:	196.50	
Converted:	6/13/2000	Receipt: 40503	CR-2000-0032465	163.50
			Total:	163.50

Attorneys

Horrocks, Michael Blaine (Primary attorney) Send Notices

Register of Actions

2/22/2000	NEWC	New Case Filed	McGee, Daniel J
	AOND	Affi And Order Of Prob Cause	McGee, Daniel J
	HRSC	Hearing Scheduled - Initial Contact (03/03/2000) Daniel J Mcgee	McGee, Daniel J
2/23/2000	BNDC	Bond Posted - Cash	McGee, Daniel J
	NTD	Notice To Defendant	McGee, Daniel J

First Judicial District Court - Shoshone County
Complete Case History
CR-2000-0032465
State of Idaho vs. Madeline M Creevy

Register of Actions

3/6/2000	FTAH	Failure To Appear For Hearing Or Trial - Initial Contact	McGee, Daniel J
	FTAW	Failure To Appear Warrant Issued	McGee, Daniel J
	WARQ	Warrant Quashed Atty Made Appearance	Clerks, Magistrate Court
	APPR	Appearance Through Attorney	McGee, Daniel J
	RFD	Request For Discovery	McGee, Daniel J
3/8/2000	HRSC	Hearing Scheduled - Pre-trial (05/12/2000) Daniel J Mcgee	
	JTSC	Jury Trial Scheduled - Jury Trial (06/15/2000) Daniel J Mcgee	McGee, Daniel J
3/17/2000	SRFD	State's Req For Discovery	McGee, Daniel J
5/11/2000	HRVC	Hearing Vacated - Pre-trial	McGee, Daniel J
	HRVC	Hearing Vacated - Jury Trial	McGee, Daniel J
	HRSC	Hearing Scheduled - Change Of Plea (06/13/2000) Daniel J Mcgee	McGee, Daniel J
6/13/2000	CPGT	Change Plea To Guilty Before H/t - Change Of Plea	McGee, Daniel J
	WHJD	Withheld Judgment Entered	McGee, Daniel J
	SNFI	Sentenced To Fine And Incarceration	McGee, Daniel J
	PROB	Probation Ordered	McGee, Daniel J
	PAA	Plea Agreement/authorization	McGee, Daniel J
	BVEX	Bond Converted / Exonerated	McGee, Daniel J
	CSCP	Case Status Closed But Pending	McGee, Daniel J
8/29/2000	NOW	Notice Of Withdrawal / Blain Horrocks	McGee, Daniel J
9/6/2005	STAT	STATUS CHANGED (batch process)	

Bench Warrant

Issued	Status	Status Date	Served By	Expires
3/6/2000	Quashed	3/6/2000		

Failure to appear on 03/03/2000, 01:15 PM, at Magistrate Court
Initial Contact

First Judicial District Court - Shoshone County
Complete Case History
CR-2000-0032465

State of Idaho vs. Madeline M Creevy

Charges

Charge: 199907 I37-2732(C)(3) Controlled Substance-possession Of Degree M

Comment:
Violation Date: 2/18/2000 03:48 PM

Officer: Andrich, Ed, 2000 Police Reference:
Disposition Date: 6/13/2000 Comment:
Plea: Guilty Finding: Guilty
Other Finding:

Sentencing Defer Date:
Modified Sentence: No Modified Sentence Date:
Jurisdiction: Retained: No Retained Days: Relinquished:
License Suspension: Years: Months: Days:
Suspended: Suspension reported:
Complied: Compliance reported:
Citation: 9473 Appearance Date: 3/3/2000 Accident: No
Cited Speed: Posted Speed: Hazardous Material: Commercial Vehicle:
Drivers License: [redacted] MT Vehicle Plate:
ITD Reported:
BCI Reported Date: 7/3/2000 Withheld Reported Date: 6/19/2000
JCA Reported Date: Agency Reported Date: 6/16/2000
F and G Reimbursement: N F and G Meat Processing Fee: N Interlock Device:

Confinement Complete By: Years: Months: Days: 30
Jail
Suspended: 30
Credited Time: No
Home:
Discretionary:
Penitentiary Determinate:
Penitentiary Indeterminate:
Juvenile:
Other:
Withheld: 1

Charge Withheld Result: Withheld Result Date:
Concurrent Sentences:
Consecutive Sentences:
Commuted Sentence: No Penitentiary Suspended: N
Life Sentence: No Death Sentence: No
Comment:

Probation: Started: 6/13/2000 Complete by: 6/13/2001 Years: 1 Months: Days:
Unsupervised Completed: Y

Fines/Fees

Description	Type	Amount	Date
Fine	Original	100.00	6/13/2000

First Judicial District Court - Shoshone County
Complete Case History
CR-2000-0032465
State of Idaho vs. Madeline M Creevy

Charges
Fines/Fees

Description	Type	Amount		Date
	Payment	-100.00	Receipt: 40503	6/13/2000
	Item total:	0.00		
Court Costs	Original	17.50		6/13/2000
	Payment	-17.50	Receipt: 40503	6/13/2000
	Item total:	0.00		
POST Fee	Original	6.00		6/13/2000
	Payment	-6.00	Receipt: 40503	6/13/2000
	Item total:	0.00		
Victim Comp.	Original	25.00		6/13/2000
	Payment	-25.00	Receipt: 40503	6/13/2000
	Item total:	0.00		
Administrative Surcharge	Original	10.00		6/13/2000
	Payment	-10.00	Receipt: 40503	6/13/2000
	Item total:	0.00		
ISTARS Tech Fund	Original	5.00		6/13/2000
	Payment	-5.00	Receipt: 40503	6/13/2000
	Item total:	0.00		
	Fine and Fees Total:	0.00		

I certify this is a copy of the court record on 4/26/18 **Date.**

Debi Bruffy
Deputy Clerk

FIRST JUDICIAL DISTRICT SHOSHONE COUNTY
CLERK OF COURT
STATE OF IDAHO

I, Madeleine Creevy McNally, **certify that as the designated representative for** Xttrium Laboratories, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MM I am at least 21 years of age;
3. MM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Madeleine Creevy McNally
Print Name (First, Last)

Madeleine Creevy McNally
Original Signature (electronic, copies or stamps not accepted)

2/24/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Madeleine Creevy McNally

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02-24-2026

Date

Please have this section completed in the presence of a Notary Public.

State of IL, ss. County of COOK

I, Madeleine Creevy McNally, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature Madeleine Creevy McNally

02/24/2026

Date

Subscribed and Sworn to before me this 24th day of Feb. 2026.

Vijay Verma

Notary Public Signature

OFFICIAL SEAL
VIJAY KUMAR VERMA
Notary Public, State of Illinois
Commission No 1009228
My Commission Expires April 28, 2029

(Seal)

List of employees

Xttrium Laboratories, Inc.
List of Employees

Madeleine Creevy McNally
Douglas Comerford
Felipe Sanchez
David Linares
Ramon Perez
Rufino Arreguin
Juan Carlos Ruiz

(773) 268 5800 3400 West Lake Avenue, Glenview, Illinois 60026 www.xttrium.com

13

13A

The purpose of this application is to provide notification of a change in ownership for Knoa Pharma LLC (anticipated May 1, 2026) - see Attachment A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler See Attachment A ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03785	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Knoa Pharma LLC

Physical Address: 201 Tresser Boulevard

City: Stamford State: CT Zip: 06901

Mailing Address (if different from physical address): 201 Tresser Blvd., Attn: Law Dept., Licensing Coordinator

City: Stamford State: CT Zip: 06901

Telephone: 203-588-8000 Website: www.knoapharma.com

Name of Designated Representative (DR): Michael Ronning

Licensing Company Email: knoa.applications@pharma.com DR Email: michael.ronning@pharma.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	■ Dangerous Drugs	■ Manufacturer (virtual manufacturer)
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Repackagers		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? See Attachment A	✓	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? See Attachment A	✓	
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 & 4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/21/2020	TBD	NJ		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		US District Court for the District of New Jersey		
Reason/Charge				
Plea agreement				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
US Department of Justice / Purdue Pharma L.P.				
Name of Business/Industry/Entity				
Purdue Pharma L.P.				

Provide explanation below:

On November 18, 2025, a plan of reorganization (the "Plan") was approved in the bankruptcy cases of Purdue Pharma LP ("PPLP") and its affiliates that are pending under the caption In re Purdue Pharma L.P. et al., Case No. 19-23649 (SHL) (Bnkr. S.D.N.Y.) (the "Chapter 11 Cases"). Pursuant to the Plan, PPLP will not emerge from bankruptcy. Instead, substantially all of the assets of PPLP (including ownership of its current direct and indirect subsidiaries) will be transferred to Knoa Pharma LLC ("KPLLC"), a new entity that was formed to receive these assets. KPLLC, in turn, will be wholly owned by a 501(c)(4) non-profit foundation that will be formed prior to KPLLC's emergence from bankruptcy. As a result of the Plan's implementation, all of PPLP's current direct and indirect subsidiaries will become wholly owned by KPLLC, undergo a conversion to limited liability companies, and the subsidiary currently known as Purdue Pharmaceuticals L.P. will change its name to Knoa Pharmaceuticals LLC. KPLLC and its subsidiaries, including Knoa Pharmaceuticals LLC and Rhodes Pharmaceuticals LLC, will have no affiliation with PPLP following implementation of the Plan. However, in the interest of transparency we note:

On October 21, 2020, PPLP entered a plea agreement with the United States Department of Justice ("DOJ") to resolve DOJ's criminal and civil investigations of PPLP*. Pursuant to the PPLP Plea Agreement, on November 24, 2020, PPLP pled guilty before the U.S. District Court for the District of New Jersey (the "NJ District Court") to three felony counts to resolve all potential criminal charges against PPLP and its subsidiaries and affiliates with respect to the production, sale, marketing and distribution of opioid products between May 2007 and the present. Neither KPLLC nor any of PPLP's subsidiaries were charged with any violations of law and none are parties to PPLP's resolution with the DOJ.

Under the terms of the PPLP Plea Agreement, PPLP is expected to be sentenced approximately seven days before the Plan becomes effective, which is currently anticipated to occur on or around May 1, 2026. A judgment of conviction will follow after PPLP's sentencing hearing is concluded.**

*The Plea Agreement and Civil Settlement Agreement comprising the proposed resolution are available at https://www.justice.gov/opa/press-release/file/1329576/download.

**While PPLP's guilty plea has been accepted by the NJ District Court, the PPLP Plea Agreement permits PPLP to withdraw its guilty plea in certain circumstances. Of remaining relevance, these include if: (1) the U.S. Department of Health and Human Services Office of Inspector General exercises, or states an intent to exercise, any available authority to exclude KPLLC from participation in federal healthcare programs; or (2) at sentencing, the NJ District Court rejects the Plea Agreement and the agreed disposition.

M. Ramos

Original Signature (electronic, copies or stamps not accepted)

4/20/26

Date

Attachment A

Statement Regarding Bankruptcy Emergence and Certain Disciplinary Actions

THE ANTICIPATED CHANGE OF CONTROL IS EXPECTED TO BE EFFECTIVE AS OF **MAY 1, 2026**, AS FURTHER DESCRIBED BELOW.

The answers provided in this application (including with respect to disciplinary matters) are expected to be true as of the date of effectiveness of the license requested. In addition, we provide the following in the interest of clarity.

On November 18, 2025, a plan of reorganization (the "Plan") was approved in the bankruptcy cases of Purdue Pharma LP ("PPLP") and its affiliates that are pending under the caption *In re Purdue Pharma L.P. et al.*, Case No. 19-23649 (SHL) (Bnkr. S.D.N.Y.) (the "Chapter 11 Cases"). Pursuant to the Plan, PPLP will not emerge from bankruptcy. Instead, substantially all of the assets of PPLP (including ownership of its current direct and indirect subsidiaries) will be transferred to Knoa Pharma LLC ("KPLLC"), a new entity that was formed to receive these assets. KPLLC, in turn, will be wholly owned by a 501(c)(4) non-profit foundation that will be formed prior to KPLLC's emergence from bankruptcy. As a result of the Plan's implementation, all of PPLP's current direct and indirect subsidiaries will become wholly owned by KPLLC, undergo a conversion to limited liability companies, and the subsidiary currently known as Purdue Pharmaceuticals L.P. will change its name to Knoa Pharmaceuticals LLC. The details of these changes are illustrated in diagrams on the succeeding pages.

KPLLC and its subsidiaries, including Knoa Pharmaceuticals LLC and Rhodes Pharmaceuticals LLC, will have no affiliation with PPLP following implementation of the Plan. However, in the interest of transparency we note:

1. On October 21, 2020, PPLP entered a plea agreement with the United States Department of Justice ("DOJ") to resolve DOJ's criminal and civil investigations of PPLP.[1] Pursuant to the PPLP Plea Agreement, on November 24, 2020, PPLP pled guilty before the U.S. District Court for the District of New Jersey (the "NJ District Court") to three felony counts to resolve all potential criminal charges against PPLP and its subsidiaries and affiliates with respect to the production, sale, marketing and distribution of opioid products between May 2007 and the present. Neither KPLLC nor any of PPLP's subsidiaries were charged with any violations of law and none are parties to PPLP's resolution with the DOJ.

   Under the terms of the PPLP Plea Agreement, PPLP is expected to be sentenced approximately seven days before the Plan becomes effective, which is currently anticipated

[1] The Plea Agreement and Civil Settlement Agreement comprising the proposed resolution are available at https://www.justice.gov/opa/press-release/file/1329576/download.

to occur on or around May 1, 2026. A judgment of conviction will follow after PPLP's sentencing hearing is concluded.[2]

2. Pursuant to the Chapter 11 Cases, a preliminary injunction is in effect that, among other things, enjoins proceedings relating to PPLP's prescription opioid business (including any actions brought by a governmental agency) that were or could have been commenced prior to the Chapter 11 Cases have been enjoined (the "Preliminary Injunction").

   Notwithstanding the foregoing, in April 2023, the State of Ohio Board of Pharmacy ("Ohio BOP") notified PPLP of a proposed disciplinary action ("Ohio Notice"), which alleges substantially similar facts or causes of action as those alleged in proceedings that are already subject to the Preliminary Injunction. Accordingly, we believe the Ohio Notice is enjoined by the Preliminary Injunction and does not constitute a pending action. Even if this is not the case, the Ohio Notice has no basis because it relies solely on PPLP's guilty plea which, pursuant to the PPLP Plea Agreement and as discussed in footnote 2 above, may be withdrawn prior to sentencing.

[2] While PPLP's guilty plea has been accepted by the NJ District Court, the PPLP Plea Agreement permits PPLP to withdraw its guilty plea in certain circumstances. Of remaining relevance, these include if: (1) the U.S. Department of Health and Human Services Office of Inspector General exercises, or states an intent to exercise, any available authority to exclude KPLLC from participation in federal healthcare programs; or (2) at sentencing, the NJ District Court rejects the Plea Agreement and the agreed disposition.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attachment B

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Knoa Foundation Inc.

Corporation/Organization Name: Knoa Pharma LLC

Mailing Address: 201 Tresser Blvd., Attn: Law Dept., Licensing Coordinator

City: Stamford State: CT Zip: 06901

Telephone: 203-588-8000 Email: knoa.applications@pharma.com

Contact Person Name: Emily Casinelli

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification n/a 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration See Attachment B 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment D	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.** n/a - see Attachment D for officers		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment E	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** See Attachment B	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment H	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment G	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8) n/a				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Knoa Pharma LLC

Facility Name

Michael Ronning

Print Name of Authorized Person Submitting Application

M Ronning

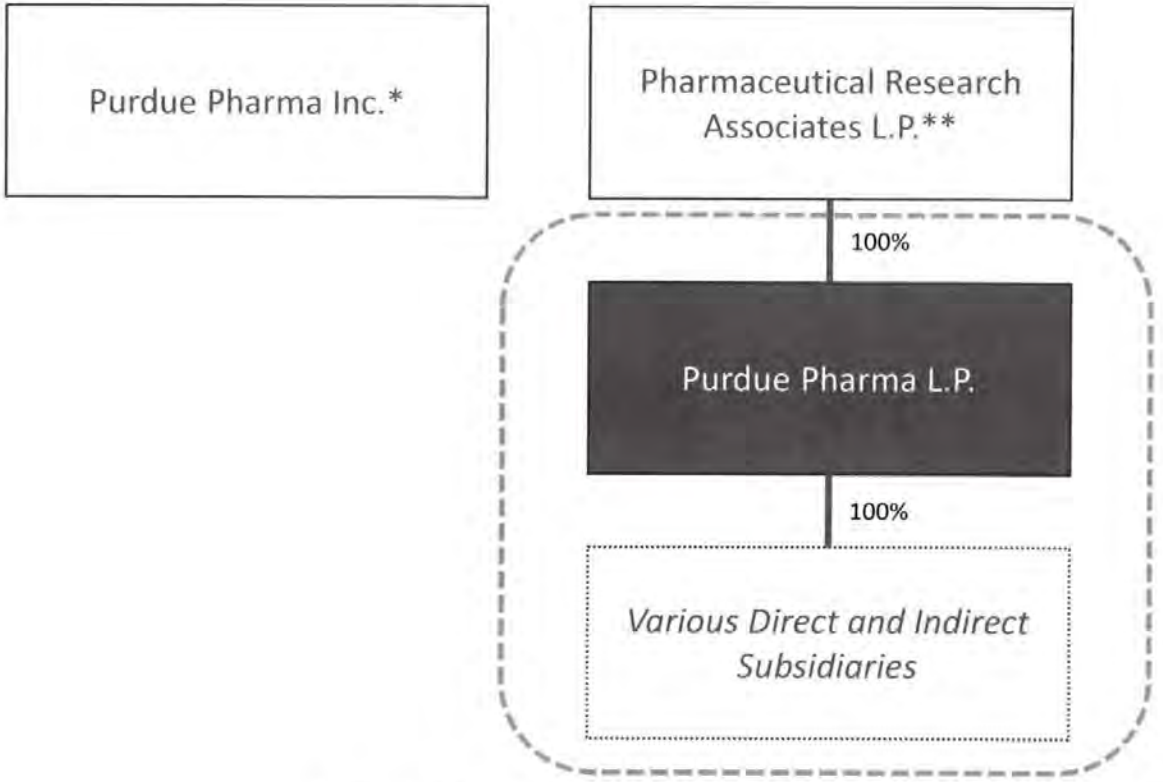
Original signature of Authorized Person (copies or stamps not accepted)

4/20/26

Date

Board Use Only	Date Received: 4/29/26	Amount: $1000 ck 105050

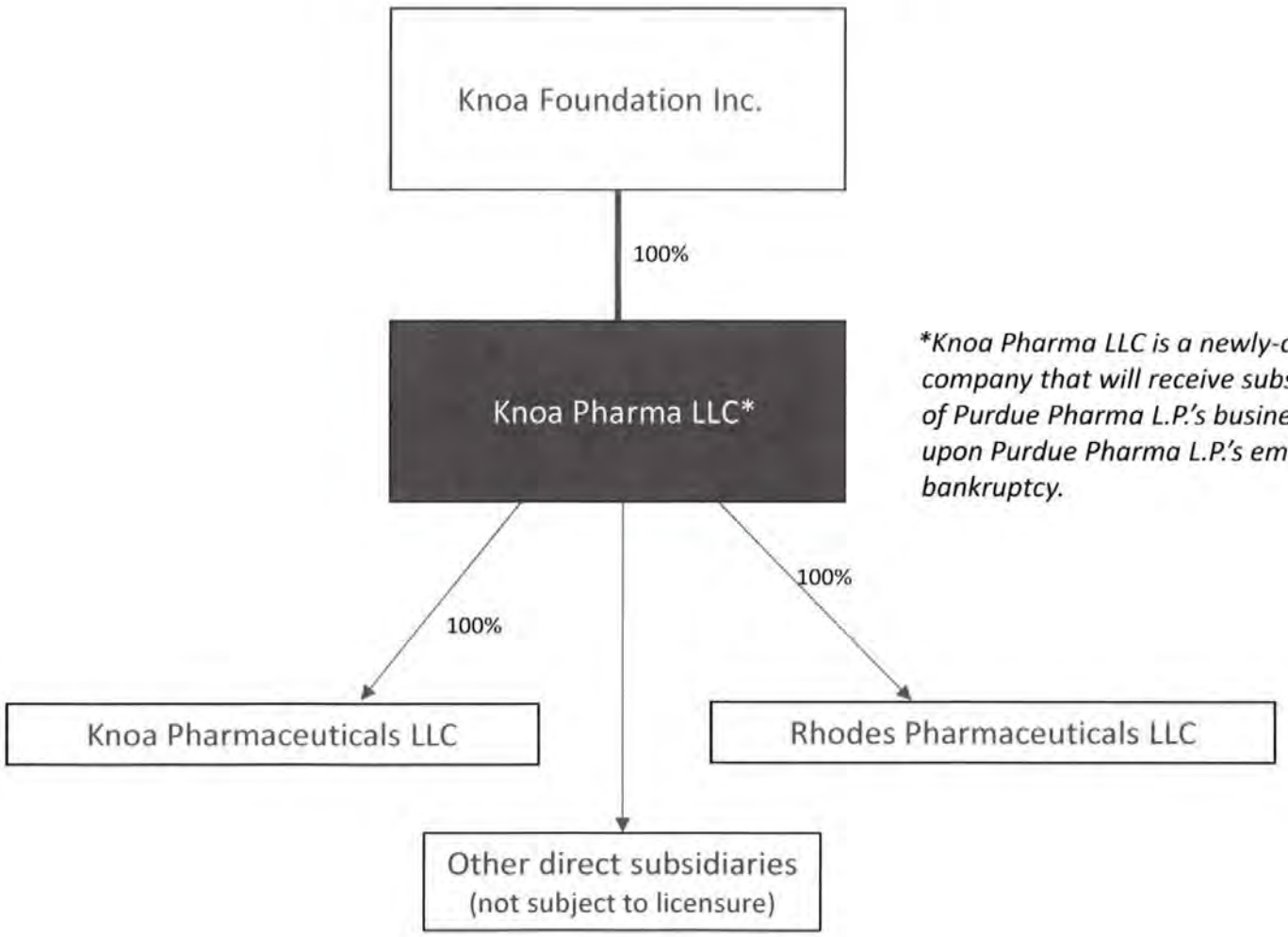
Pre-Emergence Structure



* *Purdue Pharma Inc. is the general partner of each entity inside of the dashed green border but has no equity interest in such entities.*

** *The ultimate owners of Pharmaceutical Research Associates L.P. are trusts 50 percent for the benefit of the family of Mortimer Sackler and 50 percent for the benefit of the family of Raymond Sackler.*

Post-Emergence Structure



**Knoa Pharma LLC is a newly-created company that will receive substantially all of Purdue Pharma L.P.'s business and assets upon Purdue Pharma L.P.'s emergence from bankruptcy.*

Attachment B

Description of Operations

Knoa Pharma LLC, or "Knoa" will be a virtual manufacturer of prescription drugs for human use in compliance with current good manufacturing practices. Knoa will not physically handle trade product at its business office. Other locations will be used to manufacture and distribute its product. A subsidiary, Knoa Pharmaceuticals LLC (currently known as Purdue Pharmaceuticals L.P.), will be used to ship product on behalf of Knoa. Upon request, DEA registrations in the name of Knoa Pharmaceuticals LLC will be provided after they are received by Knoa Pharmaceuticals. The current DEA registration number for the shipping location is: RP0364137.

Upon the effectiveness of the change of control the labeler code 59011 will be transferred from Purdue Pharma L.P. to Knoa and the following products will be listed in the FDA drug listing database under the labeler code 59011.

Top four suppliers Knoa has been associated with in regard to pharmaceutical products sold, dispensed or distributed over the past year: Knoa does not sell, dispense or distribute pharmaceutical products directly to customers located in Nevada, but the following CMOs are used by Knoa:

Manufacturers:
Purdue Pharmaceuticals L.P. (to become Knoa Pharmaceuticals LLC)
4701 International Boulevard W, Wilson, NC 27893
FEI: 3002960808

LTS Lohmann Therapy Systems Corp.
21 Henderson Dr., West Caldwell, NJ 07006-6607
FEI: 1000121692

Antares Pharma Inc.
12500 Whitewater Dr., Minnetonka, MN 55343
FEI: 2182861

PCI San Diego Inc./ Ajinomoto Althea
11040 Roselle Street, San Diego, CA 92121
FEI: 3004575449

Pharmascience Inc.
100 Boulevard de L'industrie, Candiac,
QC J5R 1J1, Canada (CAN)
FEI: 3002806578

The following page has a list of Knoa's products.

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

National Drug Code Directory

Current through May 06, 2026

You have searched Finished drug products

Search Results: *'59011'*

Back to Search Page () | Search Again ()

CSV Excel

Display 50 records per page

Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date
Butrans	59011-750-04	5 ug/h	PATCH, EXTENDED RELEASE	TRANSDERMAL	NDA021306	Knoa Pharma LLC	59011-750	buprenorphine	BUPRENORPHINE	HUMAN PRESCRIPTION DRUG	02/14/2011
Butrans	59011-751-04	10 ug/h	PATCH, EXTENDED RELEASE	TRANSDERMAL	NDA021306	Knoa Pharma LLC	59011-751	buprenorphine	BUPRENORPHINE	HUMAN PRESCRIPTION DRUG	02/14/2011
Butrans	59011-752-04	20 ug/h	PATCH, EXTENDED RELEASE	TRANSDERMAL	NDA021306	Knoa Pharma LLC	59011-752	buprenorphine	BUPRENORPHINE	HUMAN PRESCRIPTION DRUG	02/14/2011
Butrans	59011-757-04	7.5 ug/h	PATCH, EXTENDED RELEASE	TRANSDERMAL	NDA021306	Knoa Pharma LLC	59011-757	buprenorphine	BUPRENORPHINE	HUMAN PRESCRIPTION DRUG	02/14/2011
Butrans	59011-758-04	15 ug/h	PATCH, EXTENDED RELEASE	TRANSDERMAL	NDA021306	Knoa Pharma LLC	59011-758	buprenorphine	BUPRENORPHINE	HUMAN PRESCRIPTION DRUG	02/14/2011
Hysingla ER	59011-271-60	20 mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA206627	Knoa Pharma LLC	59011-271	hydrocodone bitartrate	HYDROCODONE BITARTRATE	HUMAN PRESCRIPTION DRUG	01/15/2015
Hysingla ER	59011-272-60	30 mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA206627	Knoa Pharma LLC	59011-272	hydrocodone bitartrate	HYDROCODONE BITARTRATE	HUMAN PRESCRIPTION DRUG	01/15/2015
Hysingla ER	59011-273-60	40 mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA206627	Knoa Pharma LLC	59011-273	hydrocodone bitartrate	HYDROCODONE BITARTRATE	HUMAN PRESCRIPTION DRUG	01/15/2015
Hysingla ER	59011-274-60	60 mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA206627	Knoa Pharma LLC	59011-274	hydrocodone bitartrate	HYDROCODONE BITARTRATE	HUMAN PRESCRIPTION DRUG	01/15/2015
Hysingla ER	59011-275-60	80 mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA206627	Knoa Pharma LLC	59011-275	hydrocodone bitartrate	HYDROCODONE BITARTRATE	HUMAN PRESCRIPTION DRUG	01/15/2015
Hysingla ER	59011-276-60	100 mg/1	TABLET, EXTENDED RELEASE	ORAL	NDA206627	Knoa Pharma LLC	59011-276	hydrocodone bitartrate	HYDROCODONE BITARTRATE	HUMAN PRESCRIPTION DRUG	12/02/2016
NALMEFENE HYDROCHLORIDE	59011-960-10	1 mg/mL	INJECTION, SOLUTION	INTRAMUSCULAR; INTRAVENOUS; SUBCUTANEOUS	ANDA212955	Knoa Pharma LLC	59011-960	NALMEFENE HYDROCHLORIDE	NALMEFENE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	02/08/2022

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date
OxyContin	59011-410-10	10 mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA022272	Knoa Pharma LLC	59011-410	oxycodone hydrochloride	OXYCODONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/08/2010
OxyContin	59011-410-20	10 mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA022272	Knoa Pharma LLC	59011-410	oxycodone hydrochloride	OXYCODONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/08/2010
OxyContin	59011-415-10	15 mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA022272	Knoa Pharma LLC	59011-415	oxycodone hydrochloride	OXYCODONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/08/2010
OxyContin	59011-415-20	15 mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA022272	Knoa Pharma LLC	59011-415	oxycodone hydrochloride	OXYCODONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/08/2010
OxyContin	59011-420-10	20 mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA022272	Knoa Pharma LLC	59011-420	oxycodone hydrochloride	OXYCODONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/08/2010
OxyContin	59011-420-20	20 mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA022272	Knoa Pharma LLC	59011-420	oxycodone hydrochloride	OXYCODONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/08/2010
OxyContin	59011-430-10	30 mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA022272	Knoa Pharma LLC	59011-430	oxycodone hydrochloride	OXYCODONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/08/2010
OxyContin	59011-430-20	30 mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA022272	Knoa Pharma LLC	59011-430	oxycodone hydrochloride	OXYCODONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/08/2010
OxyContin	59011-440-10	40 mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA022272	Knoa Pharma LLC	59011-440	oxycodone hydrochloride	OXYCODONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/08/2010
OxyContin	59011-440-20	40 mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA022272	Knoa Pharma LLC	59011-440	oxycodone hydrochloride	OXYCODONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/08/2010
OxyContin	59011-460-10	60 mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA022272	Knoa Pharma LLC	59011-460	oxycodone hydrochloride	OXYCODONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/08/2010
OxyContin	59011-460-20	60 mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA022272	Knoa Pharma LLC	59011-460	oxycodone hydrochloride	OXYCODONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/08/2010

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date
OxyContin	59011-480-10	80 mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA022272	Knoa Pharma LLC	59011-480	oxycodone hydrochloride	OXYCODONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/08/2010
OxyContin	59011-480-20	80 mg/1	TABLET, FILM COATED, EXTENDED RELEASE	ORAL	NDA022272	Knoa Pharma LLC	59011-480	oxycodone hydrochloride	OXYCODONE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/08/2010
Zurnai	59011-962-01	1.5 mg/.5mL	INJECTION, SOLUTION	INTRAMUSCULAR; SUBCUTANEOUS	NDA218590	Knoa Pharma LLC	59011-962	NALMEFENE HYDROCHLORIDE	NALMEFENE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	08/07/2025

Showing 1 to 27 of 27 entries

Previous 1 Next

Background Information (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

Drug questions email: DRUGINFO@FDA.HHS.GOV (mailto:DRUGINFO@FDA.HHS.Gov)

See also: Drug Registration and Listing Instructions (https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm)
National Drug Code Directory Data Files (https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

From: Ruta, Erin <Erin.Ruta@pharma.com>
Sent: Wednesday, July 8, 2026 6:49 AM
To: Maria Herrera <m.herrera@pharmacy.nv.gov>
Cc: Knoa Pharma Licensure Applications <knoa.applications@pharma.com>
Subject: FW: **Knoa Pharma LLC** Officer List Update - Wholesaler - Lic. # **WH03785**

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.
Good morning, Maria:

This serves as notification regarding changes to the officers of **Knoa Pharma LLC**. The updated officers list is as follows (changes shown in bold):

Name	**Position**
Michael Goettler	President & Chief Executive Officer
Keith Darragh	Executive Vice President and Chief Financial Officer
Roxana Aleali	Vice President, General Counsel & Corporate Secretary
Sailaja Bhaskar, Ph.D.	Vice President, Clinical Research & Development
Sajjan Daniel	Vice President, Drug Safety & Pharmacovigilance
Julie Ducharme	Vice President, Chief Scientific Officer
Margaret Feltz	Vice President, Chief Compliance Officer
Hussein Ghnaimeh	Vice President, Chief Information & Technology Officer
Monica Kwarcinski	Vice President, Medical Affairs
Karen Laurel	Vice President, Human Resources
Donogh McGuire	Vice President, Chief of Technical Operations

Joseph Northington	Vice President, Quality
Michael Ronning	Vice President, Sales and Marketing
Michele Sharp	Vice President, Corporate Communications & CSR

Please contact me if a specific form is required to process this change or if you have any questions.

Best regards,

Erin Ruta
Manager, Corporate Law
e: erin.ruta@pharma.com
p: 475-400-7871
a: 201 Tresser Blvd. | Stamford, CT 06901



Attachment D

LLC Officer Information

Knoa Pharma LLC
201 Tresser Boulevard
Stamford, CT 06901

Marc L. Kesselman, Chief Legal Officer & Executive Vice President, Strategy and Corporate Affairs

Keith Darragh, Executive Vice President, Chief Financial Officer

Roxana Aleali, Vice President, General Counsel & Corporate Secretary

Julie Ducharme, Vice President, Chief Scientific Officer

Karen Laurel, Vice President, Human Resources

Donogh McGuire, Vice President, Chief of Technical Operations

Michael Ronning, Vice President, Sales and Marketing

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "KNOA PHARMA LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTH DAY OF JANUARY, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "KNOA PHARMA LLC" WAS FORMED ON THE SECOND DAY OF SEPTEMBER, A.D. 2021.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 202715357

Date: 01-05-26

6211241 8300

SR# 20260017849

You may verify this certificate online at corp.delaware.gov/authver.shtml

Secretary of the State of Connecticut
Certificate of Legal Existence

Certificate of Legal Existence Certificate

Date Issued: Tuesday, December 23, 2025 9:05 AM

I, the Connecticut Secretary of the State, and keeper of the seal thereof, do hereby certify that the below limited liability company organized under the laws of UNITED STATES / DELAWARE and transacting business in the state of Connecticut filed an application for certificate of registration to transact business in this office.

A certificate of withdrawal of registration has not been filed, and so far, as indicated by the records of this office, such limited liability company is authorized to transact business in Connecticut.

Business Details

Business Name in State of Formation	KNOA PHARMA LLC
Name used to transact Business in Connecticut	KNOA PHARMA LLC
Business ALEI	US-CT.BER:2358774
Registration Date	09/17/2021

Secretary of the State

Business ALEI: US-CT.BER:2358774 Certificate Number: C-00192475

Note: To verify this certificate, visit Business.ct.gov

STATE OF CONNECTICUT
DEPARTMENT OF CONSUMER PROTECTION

This is your registration certificate for your records. Such registration shall be shown to any properly interested person on request. Do not attempt to make any changes or alter this certificate in any way. This registration is not transferable. Questions can be emailed to the Drug Control Division at dcp.drugmanufacturers@ct.gov.

In an effort to be more efficient and Go Green, the department asks that you keep your email information with our office current to receive correspondence. All renewal notifications and certificates will only be emailed to your last reported email on record. You can update your email, mailing address or print a duplicate certificate by logging into your account with your User ID and Password at www.elicense.ct.gov. Visit our website at www.ct.gov/dcp.

Mailing address:

KNOA PHARMA LLC
201 TRESSER BLVD
STAMFORD, CT 06901-3431

Email on file to be used for receiving all notices from this office:

knoa.applications@pharma.com

1159319

STATE OF CONNECTICUT ✦ DEPARTMENT OF CONSUMER PROTECTION

Be it known that

KNOA PHARMA LLC
201 TRESSER BLVD
STAMFORD, CT 06901-3431

has satisfied the qualifications required by law and is hereby issued a

MANUFACTURER OF DRUGS, COSMETICS & MEDICAL DEVICES - IN STATE

Controlled Substances: Yes **Rx Legend Drugs: Yes** **Non Rx Legend Drugs: No** **Medical Devices: No** **Cosmetics: No**

Medical Gases and Oxygen: No **Durable Medical Equipment (DME): No** **Number of Chemists: 8**

Registration #: CSM.0003242
Effective Date: 05/01/2026
Expiration Date: 06/30/2027

verify online at www.elicense.ct.gov

Bryan T. Cafferelli, Commissioner

WESTCHESTER FIRE INSURANCE COMPANY

BOND RIDER

This Bond Rider ("Rider") is to be attached to and made part of part of the Pharmaceutical Wholesaler Surety Bond **(each which bear bond number K13519031)**.

WHEREAS, Westchester Fire Insurance Company, ("Surety") as surety, issued and/or executed that certain Pharmaceutical Wholesaler Surety Bond (together with any and all rider(s) and/or amendment(s) thereto, individually and collectively, the "Bond"), bearing bond number K13519031, on behalf of Purdue Pharmaceuticals L.P., Rhodes Pharmaceuticals L.P. and Purdue Pharma L.P., as principals, in favor of the Nevada State Board of Pharmacy, as obligee, having a penal sum of $100,000.00; and,

WHEREAS, in connection with that certain Eighteenth Amended Joint Chapter 11 Plan of Purdue Pharma L.P. and its Affiliated Debtors [Docket No. 8233] (together with all plan supplements as amended, modified, or supplemented from time to time, the "Plan") entered in the chapter 11 bankruptcy case titled *In re Purdue Pharma L.P. et al.*; which is pending in the United States Bankruptcy Court for the Southern District of New York (Case No. 19-23649 (jointly administered)), and that certain Findings of Fact, Conclusions of Law, and Order Confirming the Eighteenth Amended Joint Chapter 11 Plan of Purdue Pharma L.P. and its Affiliated Debtors ("Confirmation Order") [Docket No. 8263] confirming the Plan and whereby the Plan was substantially consummated and became effective on May 1, 2026 [Docket No.9133]; and,

WHEREAS, pursuant to the Plan, there has been a change to the corporate structure of Purdue Pharma L.P. and its Debtor Affiliates whereby Knoa Pharma LLC, Rhodes Pharmaceuticals LLC and Knoa Pharmaceuticals LLC ("Knoa") are deemed Principals on the Bond, and whereas Purdue Pharma L.P. transferred all of its assets and business to Knoa Pharma LLC and is no longer operating, and Rhodes Pharmaceuticals L.P. and Purdue Pharmaceuticals L.P. each converted their respective form from a limited partnership to a limited liability company and Purdue Pharmaceuticals changed its name, and by execution of this Rider, Knoa consents to the terms set forth herein; and,

In consideration of matters and terms described herein, the Surety and Knoa (jointly, the "Parties") each hereby consent to changing the name/identity of the Principal on the Bond, as follows:

> From: Purdue Parma L.P., Rhodes Pharmaceuticals L.P. and Purdue Pharmaceuticals L.P.
>
> To: Knoa Pharma LLC, Rhodes Pharmaceuticals LLC and Knoa Pharmaceuticals LLC

Except for the change of the name/identity of the Principals on the Bond ("Name Change"), neither this Rider nor the Plan or Confirmation Order varies, alters or extends any provision or condition of the Bond. Except for the Name Change, the Bond remains in full force and effect from the date

of its initial issuance in accordance with and subject to the terms and conditions of the Bond, which Bond is/are incorporated herein as if fully set forth herein, and nothing herein or in the Plan or Confirmation Order shall limit or expand, in any manner, the Surety's obligations under or in connection with the Bond.

By its execution of this Rider and otherwise, Knoa represents, warrants and agrees that it has provided any and all necessary consents to the execution of this Rider.

Signatures on this Rider that are transmitted by facsimile or email (as well as PDF copies of signatures) shall be accepted and deemed to be original signatures for all purposes and shall be binding on the parties. This Rider may be executed in counterparts; proof of this executed Rider shall require production of only one such counterpart duly executed by the party to be charged therewith.

This Rider constitutes the whole of the understanding, discussions, and agreements by and between the Parties. The terms and provisions of this Rider are contractual and not mere recitals, unless the Rider does not become effective pursuant to the terms hereof. The Parties acknowledge and agree that there have been no oral, written or other agreements of any kind as a condition precedent to, or to induce its execution and delivery of, this Rider. Any written or oral discussions conducted prior to the Effective Date of this Rider shall not in any way vary or alter the terms of this Rider.

The modification, amendment and/or waiver of this Rider, or of any of the provisions of this Rider, shall not become effective unless executed in writing by the party to be charged with such modification, amendment and/or waiver, in each case by a duly authorized representative.

This Rider is effective May 1, 2026.

Signed, sealed and dated this 12th day of May, 2026

Westchester Fire Insurance Company

By: _____
Print Name: Annette Audinot
Print Title: Attorney-In-Fact

Knoa Pharma LLC

By: KJCA
Print Name: Keith Darragh
Print Title: EVP, CFO

Rhodes Pharmaceuticals LLC

By: KJCA
Print Name: Keith Darragh
Print Title: EVP, CFO

Knoa Pharmaceuticals LLC

By: KJCA
Print Name: Keith Darragh
Print Title: EVP, CFO

[INSERT OTHER REQUIRED DOCUMENTS, *I.E.*,
NOTARIES; POWER OF ATTORNEY; ETC.]

State of New York
County of Kings } ss:

On May 12, 2026, before me, a Notary Public in and for said County and State, residing therein, duly commissioned and sworn, personally appeared

Annette Audinot

known to me to be Attorney-in-Fact of Westchester Fire Insurance Company the corporation described in and that executed the within and foregoing instrument, and known to me to be the person who executed the said instrument in behalf of the said corporation, and he duly acknowledged to me that such corporation executed the same.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal, the day and year stated in this certificate above.

My Commission Expires November 19, 2028

Terry Ann Gonzales-Selman Notary Public

TERRY ANN GONZALES-SELMAN
Notary Public, State of New York
No. 01GO6272513
Qualified in Kings County
Commission Expires November 19, 2028

Individual Acknowledgment

State of _____
County of _____

On the _____ day of _____, 20_____, before me personally appeared _____ to me known and known to me to be the person described in and who executed the foregoing instrument and ____he____ thereupon acknowledged to me that ____he___ executed the same.

_____
Notary Public

Partnership/L.L.C. Acknowledgment

State of Connecticut
County of Fairfield

On the 15th day of May, 2026, before me personally appeared Keith Darragh to me known and known to me to be one of the firm of KNOA PHARMA LLC, KNOA PHARMACEUTICALS LLC, AND Rhodes Pharmaceuticals LLC described in and who executed the foregoing instrument and _____he_____ thereupon acknowledged to me that ___he___ executed the same as and for the act and deed of said firm.

Emily P. Casinelli
Notary Public, State of Connecticut
My Commission Expires Jan. 31, 2027

Emily P. Casinelli
Notary Public

Corporate Acknowledgment

State of _____
County of _____

On the _____day of _____, 20_____, before me personally appeared _____ to me known, who being by me duly sworn, did depose and say the _____he_____ is the _____ of the _____ the corporation described in and which executed the foregoing instrument that _____he_____ knows the seal of said corporation, that the seal affixed to said instrument is such corporate seal, that it was so affixed by order of the board of directors of said corporation, and that _____he_____ signed his name thereto by like order.

_____
Notary Public

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Delaware corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint

Annette Audinot

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **19th** day of **July, 2024.**

Rupert HD Swindells Assistant Secretary

Warren Eichhorn, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss.

On this **19th** day of **July, 2024** before me, a Notary Public of New Jersey, personally came Rupert HD Swindells and Warren Eichhorn, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Rupert HD Swindells and Warren Eichhorn, being by me duly sworn, severally and each for himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

Albert Contursi
NOTARY PUBLIC OF NEW JERSEY
No 50202369
Commission Expires August 22, 2027

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Rupert HD Swindells, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this May 12, 2026

Rupert HD Swindells, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903-3493 Fax (908) 903-3656 e-mail: surety@chubb.com

WESTCHESTER FIRE INSURANCE COMPANY

STATEMENT OF ASSETS, LIABILITIES AND SURPLUS TO POLICYHOLDERS

Statutory Basis

December 31, 2025

(in thousands)

ASSETS		*LIABILITIES AND SURPLUS TO POLICYHOLDERS*	
Cash, Cash Equivalents, and ST Investments	$ 8,557	Outstanding Losses and Loss Expenses	$ -
U.S. Government Bonds	17,259	Reinsurance Payable on Losses and Expenses	-
Non-US Government Bonds	289	Unearned Premiums	-
Issuer Credit Obligations ("ICO") Bonds	7,594	Ceded Reinsurance Premiums Payable	-
Asset-Backed Securities ("ABS") Bonds	42,474	Other Liabilities	190,579
Stocks	-		
Other Invested Assets	4,428		
TOTAL INVESTMENTS	78,581	TOTAL LIABILITIES	190,579
Investments in Affiliates		Capital Stock	5,000
Premiums Receivable	-	Paid-In Surplus	40,960
Other Assets	173,325	Unassigned Funds	15,387
		SURPLUS TO POLICYHOLDERS	61,327
TOTAL ADMITTED ASSETS	$ 251,906	TOTAL LIABILITIES AND SURPLUS	$ 251,906

Investments are valued in accordance with requirements of the National Association of Insurance Commissioners. At December 31, 2025 investments with a carrying value of $11,903,096 were deposited with government authorities as required by law.

STATE OF PENNSYLVANIA

COUNTY OF PHILADELPHIA

John Taylor, being duly sworn, says that he is Senior Vice President of Westchester Fire Insurance Company and that to the best of his knowledge and belief the foregoing is a true and correct statement of the said Company's financial condition as of the 31 st day of December, 2025

Sworn before me this March 11, 2026

Senior Vice President

Jaime L. Yates

Notary Public

September 19, 2027

My commission expires

Commonwealth of Pennsylvania - Notary Seal
Jaime L. Yates, Notary Public
Philadelphia County
My commission expires September 19, 2027
Commission number 1357070

Member, Pennsylvania Association of Notaries

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. K13519031

Application/License No. _____

Purdue Pharmaceuticals L.P. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 4701 Wilson Drive, Wilson, NC 27893 (Address of Applicant/Principal), as PRINCIPAL, and Westchester Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Pennsylvania (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 436 Walnut Street, Philadelphia, PA 19106-3703 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 08, 2018 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 8th day of March, 2018.

APPLICANT/PRINCIPAL

Purdue Pharmaceuticals L.P.

Authorized Representative

SURETY COMPANY

Westchester Fire Insurance Company

Surety Company's Representative

Jessica Iannotta, Attorney-in-fact
print name
NV Non Resident Producer, License No. 3155198

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Kelly O'Malley

Witness Annette Leuschner

Countersigned by:

N/A

Nevada Resident Agent

Power of Attorney

WESTCHESTER FIRE INSURANCE COMPANY

Know all men by these presents: That WESTCHESTER FIRE INSURANCE COMPANY, a corporation of the Commonwealth of Pennsylvania pursuant to the following Resolution, adopted by the Board of Directors of the said Company on December 11, 2006, to wit:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such persons written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested.

Does hereby nominate, constitute and appoint Annette Leuschner, April D Perez, James P Holland, Jessica Iannotta, Kelly O'Malley, Kristin S Bender, Marisol Mojica, Theresa Giraldo all of the City of MORRISTOWN, New Jersey, each individually if there be more than one named, its true and lawful attorney-in-fact, to make, execute, seal and deliver on its behalf, and as its act and deed any and all bonds, undertakings, recognizances, contracts and other writings in the nature thereof in penalties not exceeding SEVENTY MILLION DOLLARS & ZERO CENTS ($70,000,000.00) and the execution of such writings in pursuance of these presents shall be as binding upon said Company, as fully and amply as if they had been duly executed and acknowledged by the regularly elected officers of the Company at its principal office,

IN WITNESS WHEREOF, the said Stephen M. Haney, Vice-President, has hereunto subscribed his name and affixed the Corporate seal of the said WESTCHESTER FIRE INSURANCE COMPANY this 3 day of October 2017

WESTCHESTER FIRE INSURANCE COMPANY

Stephen M. Haney, Vice President

COMMONWEALTH OF PENNSYLVANIA
COUNTY OF PHILADELPHIA ss.

On this 3 day of October, 2017 before me, a Notary Public of the Commonwealth of Pennsylvania in and for the County of Philadelphia came Stephen M. Haney, Vice-President of the WESTCHESTER FIRE INSURANCE COMPANY to me personally known to be the individual and officer who executed the preceding instrument, and he acknowledged that he executed the same, and that the seal affixed to the preceding instrument is the corporate seal of said Company; that the said corporate seal and his signature were duly affixed by the authority and direction of the said corporation, and that Resolution, adopted by the Board of Directors of said Company, referred to in the preceding instrument, is now in force.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my official seal at the Cityof Philadelphia the day and year first above written.

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
KAREN E. BRANDT, Notary Public
City of Philadelphia, Phila. County
My Commission Expires Sept. 26, 2018

Notary Public

I, the undersigned Assistant Secretary of the WESTCHESTER FIRE INSURANCE COMPANY, do hereby certify that the original POWER OF ATTORNEY, of which the foregoing is a substantially true and correct copy, is in full force and effect.

In witness whereof, I have hereunto subscribed my name as Assistant Secretary, and affixed the corporate seal of the Corporation, this 8th day of March 2018

Dawn M. Chloros, Assistant Secretary

THIS POWER OF ATTORNEY MAY NOT BE USED TO EXECUTE ANY BOND WITH AN INCEPTION DATE AFTER OCTOBER 03, 2019.

DocuGard #04546 contains a security pantograph, blue background, heat-sensitive ink, coin-reactive watermark, and microtext printing on border.

HEAT SENSITIVE SHIELD

WESTCHESTER FIRE INSURANCE COMPANY

FINANCIAL STATEMENT **DECEMBER 31, 2016**

ADMITTED ASSETS

BONDS	$1,492,813,519
SHORT - TERM INVESTMENTS	34,890,369
STOCKS	450,903
REAL ESTATE	0
CASH ON HAND AND IN BANK	19,880,440
PREMIUM IN COURSE OF COLLECTION*	69,254,246
INTEREST ACCRUED	14,505,011
OTHER ASSETS	132,649,982
TOTAL ASSETS	$1,764,444,470

LIABILITIES

RESERVE FOR UNEARNED PREMIUMS	$200,260,562
RESERVE FOR LOSSES	851,003,190
RESERVE FOR TAXES	16,081,016
FUNDS HELD UNDER REINSURANCE TREATIES	5,666,051
OTHER LIABILITIES	(11,412,992)
TOTAL LIABILITIES	1,061,597,827

CAPITAL: 70,000 SHARES, $71.43 PAR VALUE	5,000,100
CAPITAL: PAID IN	304,543,059
AGGREGATE WRITE-INS FOR SPECIAL SURPLUS FUNDS	113,661,643
SURPLUS (UNASSIGNED)	279,641,841
SURPLUS TO POLICYHOLDERS	702,846,643
TOTAL	$1,764,444,470

(*EXCLUDES PREMIUM MORE THAN 90 DAYS DUE.)

STATE OF PENNSYLVANIA

COUNTY OF PHILADELPHIA

John Taylor, being duly sworn, says that he is Senior Vice President of Westchester Fire Insurance Company and that to the best of his knowledge and belief the foregoing is a true and correct statement of the said Company's financial condition as of the 31 st day of December, 2016.

Sworn before me this March 22, 2017

Senior Vice President

Notary Public

August 8, 2019
My commission expires

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
Diane Wright, Notary Public
City of Philadelphia, Philadelphia County
My Commission Expires Aug. 8, 2019
MEMBER, PENNSYLVANIA ASSOCIATION OF NOTARIES

SURETY RIDER

To be attached to and form a part of

Bond No. K13519031

dated effective March 8, 2018
(MONTH-DAY-YEAR)

executed by Purdue Pharmaceuticals L.P. , as Principal,
(PRINCIPAL)

and by Westchester Fire Insurance Company , as Surety,

in favor of Nevada State Board of Pharmacy
(OBLIGEE)

in consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

Adding the Principal name to the bond as follows:

Rhodes Pharmaceuticals L.P.
498 Washington Street
Coventry, RI 02816

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective February 26, 2020
(MONTH-DAY-YEAR)

Signed and Sealed August 27, 2020
(MONTH-DAY-YEAR)

Rhodes Pharmaceuticals L.P.
(PRINCIPAL)

By: _____
(PRINCIPAL)

Westchester Fire Insurance Company
(SURETY)

By: April D. Perez
April D. Perez, Attorney-In-Fact

S-0443/GEEF 10/99

CHUBB

Power of Attorney

Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint Annette Audinot, Kristin S. Bender, Jessica Iannotta, Kelly O'Malley and April D. Perez of Morristown, New Jersey; Megan Schlueter of Raleigh, North Carolina ----------

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY have each executed and attested these presents and affixed their corporate seals on this **2nd** day of **October, 2019**.

Dawn M. Chloros

Dawn M Chloros, Assistant Secretary

Steve M Haney

Stephen M Haney, Vice President

STATE OF NEW JERSEY

County of Hunterdon ss

On this **2nd** day of **October, 2019**, before me, a Notary Public of New Jersey, personally came Dawn M. Chloros, to me known to be Assistant Secretary of WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Dawn M. Chloros, being by me duly sworn, did depose and say that she is Assistant Secretary of WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and knows the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that she signed said Power of Attorney as Assistant Secretary of said Companies by like authority; and that she is acquainted with Stephen M. Haney, and knows him to be Vice President of said Companies; and that the signature of Stephen M. Haney, subscribed to said Power of Attorney is in the genuine handwriting of Stephen M. Haney, and was thereto subscribed by authority of said Companies and in deponent's presence.

Notarial Seal

KATHERINE J. ADELAAR
NOTARY PUBLIC OF NEW JERSEY
No. 2316685
Commission Expires July 16, 2024

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006 : ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Dawn M. Chloros, Assistant Secretary of WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this August 27, 2020

Dawn M. Chloros

Dawn M Chloros, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903-3493 Fax (908) 903-3656 e-mail: surety@chubb.com

WFIC-AAIC (rev. 08-18)

DocuSign Envelope ID: CCF7D358-9B25-47C6-8B4C-6EAB7BF6431E

WESTCHESTER FIRE INSURANCE COMPANY

STATEMENT OF ASSETS, LIABILITIES AND SURPLUS TO POLICYHOLDERS

Statutory Basis

December 31, 2019

(in thousands)

ASSETS		*LIABILITIES AND SURPLUS TO POLICYHOLDERS*	
Cash and Short Term Investments	$ (17,346)	Outstanding Losses and Loss Expenses	$ -
United States Government, State and Municipal Bonds	106,879	Reinsurance Payable on Losses and Expenses	-
Other Bonds	56,172	Unearned Premiums	-
Stocks	28	Ceded Reinsurance Premiums Payable	-
Other Invested Assets	6,008	Other Liabilities	100,006
TOTAL INVESTMENTS	151,741	TOTAL LIABILITIES	100,006
Investments in Affiliates	-	Capital Stock	5,000
Premiums Receivable	-	Paid-In Surplus	59,856
Other Assets	92,830	Unassigned Funds	79,709
		SURPLUS TO POLICYHOLDERS	144,565
TOTAL ADMITTED ASSETS	$ 244,571	TOTAL LIABILITIES AND SURPLUS	$ 244,571

Investments are valued in accordance with requirements of the National Association of Insurance Commissioners. At December 31, 2019, investments with a carrying value of $12,787,328 were deposited with government authorities as required by law.

STATE OF PENNSYLVANIA

COUNTY OF PHILADELPHIA

John Taylor, being duly sworn, says that he is Senior Vice President of Westchester Fire Insurance Company and that to the best of his knowledge and belief the foregoing is a true and correct statement of the said Company's financial condition as of the 31 st day of December, 2019.

Subscribed before me this April 14, 2020

John Taylor

Senior Vice President

Diane Wright

Notary Public

August 8, 2023

My commission expires

Commonwealth of Pennsylvania - Notary Seal
Diane Wright, Notary Public
Philadelphia County
My commission expires August 8, 2023
Commission number 1235745

Member, Pennsylvania Association of Notaries

SURETY RIDER

To be attached to and form a part of

Bond No. K13519031

dated effective March 8, 2018
(MONTH-DAY-YEAR)

executed by Purdue Pharmaceuticals L.P. and Rhodes Pharmaceuticals L.P. , as Principal,
(PRINCIPAL)

and by Westchester Fire Insurance Company , as Surety,

in favor of Nevada State Board of Pharmacy
(OBLIGEE)

in consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

The Principal name to:

Purdue Pharmaceuticals L.P, Rhodes Pharmaceuticals L.P. and Purdue Pharma L.P.

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective June 13, 2024
(MONTH-DAY-YEAR)

Signed and Sealed June 13, 2024
(MONTH-DAY-YEAR)

Purdue Pharmaceuticals L.P, Rhodes Pharmaceuticals L.P. and Purdue Pharma L.P.
(PRINCIPAL)

By: _____
(PRINCIPAL)

Westchester Fire Insurance Company
(SURETY)

By: _____
TeryAnn Gonzales-Selman, Attorney-In-Fact

S-0443/GEEF 10/99

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Wisconsin corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint Annette Audinot, Terry Ann Gonzales-Selman, Robert P. McDonough, Vincent Moy, Francesca Papa and Glenn Pelletiere of New York, New York

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **30th** day of **April 2024**.

Rupert HD Swindells, Assistant Secretary

Warren Eichhorn, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss.

On this **30th** day of **April, 2024** before me, a Notary Public of New Jersey, personally came Rupert HD Swindells and Warren Eichhorn, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Rupert HD Swindells and Warren Eichhorn, being by me duly sworn, severally and each for himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

Albert Contursi
NOTARY PUBLIC OF NEW JERSEY
No 50202369
Commission Expires August 22,2027

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Rupert HD Swindells, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this June 13, 2024

Rupert HD Swindells, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903-3493 Fax (908) 903-3656 e-mail: surety@chubb.com

WESTCHESTER FIRE INSURANCE COMPANY

STATEMENT OF ASSETS, LIABILITIES AND SURPLUS TO POLICYHOLDERS

Statutory Basis

December 31, 2023

(in thousands)

ASSETS		*LIABILITIES AND SURPLUS TO POLICYHOLDERS*	
Cash, Cash Equivalents, and ST Investments	$ 6,916	Outstanding Losses and Loss Expenses	$ -
United States Government, State and		Reinsurance Payable on Losses and Expenses	-
Municipal Bonds	55,420	Unearned Premiums	-
Other Bonds	7,550	Ceded Reinsurance Premiums Payable	-
Stocks		Other Liabilities	204,011
Other Invested Assets	4,092		
TOTAL INVESTMENTS	73,978	TOTAL LIABILITIES	204,011
Investments in Affiliates	-	Capital Stock	5,000
Premiums Receivable	-	Paid-In Surplus	40,960
Other Assets	184,387	Unassigned Funds	8,394
		SURPLUS TO POLICYHOLDERS	54,354
TOTAL ADMITTED ASSETS	$ 258,365	TOTAL LIABILITIES AND SURPLUS TO POLICYHOLDERS	$ 258,365

Investments are valued in accordance with requirements of the National Association of Insurance Commissioners. At December 31, 2023, investments with a carrying value of $11,811,787 were deposited with government authorities as required by law.

STATE OF PENNSYLVANIA

COUNTY OF PHILADELPHIA

John Taylor, being duly sworn, says that he is Senior Vice President of Westchester Fire Insurance Company and that to the best of his knowledge and belief the foregoing is a true and correct statement of the said Company's financial condition as of the 31 st day of December, 2023.

Sworn before me this March 11, 2024

Senior Vice President

Notary Public

August 8, 2027
My commission expires

Commonwealth of Pennsylvania - Notary Seal
Diane Wright, Notary Public
Philadelphia County
My commission expires August 8, 2027
Commission number 1235745
Member, Pennsylvania Association of Notaries

MARSH

INVOICE

Marsh USA LLC
New York NY
(212) 345-6000

Page	1 of 2
Invoice Total	**1,000.00 USD**
Invoice No.	335535630356
Invoice Date	05/20/2026
Client No.	3355300000

Billed To:
Antoinette Green
Purdue Pharma Manufacturing L.P.
One Stamford Forum
Stamford, CT 06901

Remittance Copy

Company earns and retains interest income on premium payments held by Marsh on behalf of insurers during the period between receipt of such payments from clients and the time such payments are remitted to the applicable insurer, where permitted by law.

Detach and remit this portion with your payment

Client No.	Invoice No.	Payment Due	Invoice Total	Amount Paid
3355300000	335535630356	Immediate	1,000.00 USD	

Thank you for your prompt payment.

Please indicate Invoice Number 335535630356 on your remittance.

Additionally, for ACH or wire payments, e-mail remittance detail to: FiduciaryserviceRequest.US@marsh.com

By ACH:
Bank Name: Bank of America
ACH Routing No: 071000039
Account Title: Marsh USA LLC
Account Number: 8188063077

By Wire:
Bank Name: Bank of America
Wire Routing Number: 026009593
Account Title: Marsh USA LLC
Account Number: 8188063077

By Mail:
Marsh USA LLC
P.O. Box 846015
Dallas, TX 75284-6015 USA

3355356303564 000010000033

MARSH

INVOICE

Marsh USA LLC
New York NY
(212) 345-6000

Page	2 of 2
Invoice Total	**1,000.00 USD**
Invoice No.	335535630356
Invoice Date	05/20/2026
Client No.	3355300000

Billed To:
Antoinette Green
Purdue Pharma Manufacturing L.P.
One Stamford Forum
Stamford, CT 06901

Surety Name	Bond No.	Effective Date	Expiration Date	Transaction Type	Description/ Type of Coverage	Item	Amount
Westchester Fire Insurance Co	K13519031	03/08/2026	03/08/2027	Original	Commercial Bond	PREMIUM	1,000.00

Invoice Comments:

Principal:Purdue Pharmaceuticals L.P, Rhodes Pharmaceuticals L.P. and Purdue Pharma L.P.
Obligee:Nevada State Board of Pharmacy
Bond Amount: $100,000.00
Bond Type - Description:License & Permit - Pharmaceutical Wholesaler
Requester:Antoinette (Toni) Green

Invoice Total (Payable in Full upon Receipt)	1,000.00

Company earns and retains interest income on premium payments held by Marsh on behalf of insurers during the period between receipt of such payments from clients and the time such payments are remitted to the applicable insurer, where permitted by law.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Knoa Pharma LLC

Pharmacy/Wholesaler License # (if applicable) n/a

Physical Address 201 Tresser Boulevard

City Stamford State CT Zip 06901

Mailing Address (if different from physical address) 201 Tresser Blvd., Attn: Law Dept., Licensing Coordinator

City Stamford State CT Zip 06901

Telephone 203-588-8000 Website www.knoapharma.com

Licensing Company Email knoa.applications@pharma.com

Section 2: Personal Information

First Michael Middle T Last Ronning

Alias(es, nick[redacted], etc.) n/a

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address 201 Tresser Blvd.

City Stamford State CT Zip 06901

Telephone 203-588-8090 Email michael.ronning@pharma.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? n/a		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of New Hampshire		08/91-05/95	
Address	**City**	**State**	**Zip**
105 Main Street	Durham	NH	03824
Diploma/Degree obtained, if any			
B.S. Biochemistry			

School Name		From - To (MM/YY – MM/YY)	
Simsbury High School		09/87-06/91	
Address	**City**	**State**	**Zip**
34 Farms Village Road	Simsbury	CT	06070
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2002-Present	[redacted]	Fairfield	CT	[redacted]
From - To (MM/YY – MM/YY)	[redacted]	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Purdue Pharma L.P. (to become Knoa Pharma LLC after change of control, anticipated 5/1/26)			2009-05/2026	
Business Address		City	State	Zip
201 Tresser Blvd.		Stamford	CT	06901
Phone	Title		Number of Employed Hours	
203-588-8090	michael.ronning@pharma.com		6,000 +	

Description of Duties

Duties include, but are not limited to: Responsible for the management of the commercial organization which includes Analytics, Customer Service, Forecasting, Marketing, Market Access, Market Research, Pricing and Contracting, and Sales Organization (for non-opioids). Oversight of departmental budget(s), supply forecasts, and product introduction activities. Maintenance of critical business operations and key customer/vendor relationships.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? n/a		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/21/2020	TBD	NJ		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		US District Court for the District of New Jersey		
Reason/Charge				
Plea agreement				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
US Department of Justice / Purdue Pharma L.P.				
Name of Business/Industry/Entity				
Purdue Pharma L.P.				

Provide explanation below:

The Designated Representative worked for Purdue Pharma L.P. ("PPLP"). PPLP has a significant number of active product liability claims and litigations with various jurisdictions in the U.S., specifically related to opioid products. In order to resolve these litigations, on September 15, 2019, PPLP and certain of its subsidiaries commenced voluntary cases under Chapter 11 of title 11 of the United States Code (the "Bankruptcy Code") in the United States Bankruptcy Court for the Southern District of New York (the "Bankruptcy Court") which are pending under the caption In re Purdue Pharma L.P. et al., Case No. 19-23649 (SHL) (Bnkr. S.D.N.Y.), as more fully described in Attachment A of the application.

Original Signature (electronic, copies or stamps not accepted)

Date 4/20/26

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
4/5/2023	TBD	OH		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
A-2020-0777		Ohio Board of Pharmacy		
Reason/Charge				
Proposed disciplinary action				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Ohio Board of Pharmacy / Purdue Pharma L.P.				
Name of Business/Industry/Entity				
Purdue Pharma L.P.				

Provide explanation below:

Pursuant to the Chapter 11 Cases, a preliminary injunction is in effect that, among other things, enjoins proceedings relating to PPLP's prescription opioid business (including any actions brought by a governmental agency) that were or could have been commenced prior to the Chapter 11 Cases have been enjoined (the "Preliminary Injunction").

Notwithstanding the foregoing, in April 2023, the State of Ohio Board of Pharmacy ("Ohio BOP") notified PPLP of a proposed disciplinary action ("Ohio Notice"), which alleges substantially similar facts or causes of action as those alleged in proceedings that are already subject to the Preliminary Injunction. Accordingly, we believe the Ohio Notice is enjoined by the Preliminary Injunction and does not constitute a pending action. Even if this is not the case, the Ohio Notice has no basis because it relies solely on PPLP's guilty plea which, pursuant to the PPLP Plea Agreement and as discussed in footnote 2 above, may be withdrawn prior to sentencing.

Original Signature (electronic, copies or stamps not accepted)

Date 4/20/26

I, Michael Ronning, **certify that as the designated representative for**

Knoa Pharma LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MR I am at least 21 years of age;
3. MR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Michael Ronning

Print Name (First, Last)

M. Ronning

Original Signature (electronic, copies or stamps not accepted)

4/20/26

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Ronning

Print Name (First, Last)

M. Ronning

Original Signature (electronic, copies or stamps not accepted)

4/20/26

Date

Please have this section completed in the presence of a Notary Public.

State of CONNECTICUT, County of FAIRFIELD

I, Michael Ronning, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

M. Ronning

Original Signature

4/20/26

Date

Subscribed and Sworn to before me this 20th day of April, 2026

Emily P. Casinelli

Notary Public Signature

Emily P. Casinelli
Notary Public, State of Connecticut
My Commission Expires Jan. 31, 2027

(Seal)

Knoa Pharma LLC
201 Tresser Blvd
Stamford, CT 06901

Attachment H

List of Employees, Agents, Independent Contractors, etc. of the Applicant Statement

Please see following pages for a complete list of active Knoa Pharma LLC employees, agents, independent contractors, etc. as of May 1, 2026.

Employee Id	Employee Name	Position	Company
000116	Atherton, Michele E	Sr. Clinical Project Manager 4713208	Knoa Pharma LLC
000417	Szetela, Andrew	Manager Administrative Services	Knoa Pharma LLC
000980	Jimenez, Janet	Administrative Associate V 2200208	Knoa Pharma LLC
001374	Visciglia, Sharon E	Sr. Credit Analyst	Knoa Pharma LLC
001415	Sielert, William S	Director ERP Applications	Knoa Pharma LLC
001528	Kusinski, Lynn E	Director Benefits HRIS & Payroll	Knoa Pharma LLC
001645	Cipriano, Alessandra	Sr. Director Clinical Operations 4713208	Knoa Pharma LLC
001698	Cabral, Deolinda S	Associate Director Payroll Services	Knoa Pharma LLC
001715	Ostrowski, Christine A	Head of Pricing	Knoa Pharma LLC
001795	Burko, Deborah A	Associate Director Clinical Project Management 4713208	Knoa Pharma LLC
002104	Ramsey, Harry L	Sr. Manager Package Design & Development	Knoa Pharma LLC
002106	Kraft, Eric	Principal Scientist 4900208	Knoa Pharma LLC
002116	Evans, Susan K	Sr. Administrative Ast.	Knoa Pharma LLC
002131	Graziano, Alicia C	Director Pricing Operations	Knoa Pharma LLC
002438	Mohler, Niketa	Package Development Engineer	Knoa Pharma LLC
002538	Beck-Sechow, Jennifer K	Sr. Manager Payroll Services	Knoa Pharma LLC
002618	Iemma, Cristina D	Associate Director Drug Safety	Knoa Pharma LLC
002705	Issa, Giselle N	Director Law Dept. Operations	Knoa Pharma LLC
002751	Mitchell, Laura K	National Accounts Executive 8601208	Knoa Pharma LLC
002836	Giordano, Jennifer L	Head of Business Operations	Knoa Pharma LLC
004157	Kwarcinski, Monica A	VP Medical Affairs	Knoa Pharma LLC
004218	Shet, Manjunath S	Sr. Director PKDM 4300208	Knoa Pharma LLC
004375	Eastman, Lawrence M	Associate Director ISQA	Knoa Pharma LLC
004385	Harris, Stephen C	Head of Clinical Pharmacology 4400208	Knoa Pharma LLC
004594	Laurel, Karen A	VP Human Resources	Knoa Pharma LLC
004611	Belward, Deborah	Administrative Associate III 4717208	Knoa Pharma LLC
004792	Boykin, Deborah C	Administrative Associate V 4750208	Knoa Pharma LLC
004858	Ripa, Steven R	Executive Medical Director 4400208	Knoa Pharma LLC
004881	Ahrenberg, Jennifer D	Sr. Quality Specialist III 2190208	Knoa Pharma LLC
004970	Watson, Laura J	Director Customer Service	Knoa Pharma LLC
005130	Foldeak-Edwards, Jean M	Administrative Associate IV 8800208	Knoa Pharma LLC
005207	Meehan, Maureen	Contract Paralegal	Knoa Pharma LLC
005317	Casinelli, Emily P	Legal Specialist	Knoa Pharma LLC
005500	O'Grady, Diane	Manager Regulatory Affairs Product Labeling 4010208	Knoa Pharma LLC
005659	Wargo, Dawn M	Sr. Customer Service Rep	Knoa Pharma LLC
005690	Sessler, Nelson E	Director Clinical Development Lead 4400208	Knoa Pharma LLC
005842	Zemble, Gerald L	Sr. Quality Specialist III SQA	Knoa Pharma LLC
005898	Williams, Teresa P	Sr. QA Specialist I Batch Disposition	Knoa Pharma LLC
005934	Sullivan, Brian	Director IT Business Relationship 2450208	Knoa Pharma LLC
005954	Bhaskar, Sailaja B	VP Clinical R&D 4750208	Knoa Pharma LLC
006041	Nelson, Jacqueline O	Director Regulatory Affairs 4010208	Knoa Pharma LLC
006069	Gipson, Michael S	Sr. Quality Specialist III Auditing Team Lead	Knoa Pharma LLC
006156	Christensen, Kris	Director Mkt Access Contracting & Analytics 8800208	Knoa Pharma LLC
006292	Hedgepeth, Shelton M	Sr. QA Specialist II Batch Disposition	Knoa Pharma LLC
006330	Lauriat, Jennifer D	Sr. Manager Corporate Procurement	Knoa Pharma LLC
006510	Taylor, Tonia T	Sr. Quality Specialist II	Knoa Pharma LLC
006614	Shah, Rupa P	National Director Medical Science Liaisons	Knoa Pharma LLC
006684	Ricarte, Maria C	Asc. General Counsel Head of Lit. Risk Mgmt	Knoa Pharma LLC
006688	Sparta, Gregory V	Executive Director Regulatory Affairs 4010208	Knoa Pharma LLC
006707	Dhaliwal, Kulwant	Associate Director Sales & Distribution Systems Analysis & Support	Knoa Pharma LLC
006721	Geremia, Cynthia A	Director Information Research & Management	Knoa Pharma LLC
006798	Whiteside, Garth T	Head of Pre-Clinical Development 4300208	Knoa Pharma LLC
006812	Gandhi, Mukeshkumar T	Sr. Quality Specialist III QA Improvement 2192208	Knoa Pharma LLC
006840	MacDonald, Colleen M	Manager Law Department Technical Systems & Data	Knoa Pharma LLC
006868	Vo, Luong V	Quality Advisor 2191208	Knoa Pharma LLC
006948	Haase Jr, Kurt E	Director Infrastructure & Collaboration Svc	Knoa Pharma LLC
006956	Johnson, Alan D	Sr. Quality Advisor SQA Team Lead	Knoa Pharma LLC
007290	Bartolo, Donna M	Sr. Administrative Asc. I 2200208	Knoa Pharma LLC
007333	Reilly, Kevin G	Sr. Scientist 4900208	Knoa Pharma LLC
007355	Sisto, Laura	Sr. Packaging Design Specialist	Knoa Pharma LLC
007463	Mercer, Jeremy M	Sr. Quality Specialist III 2190208	Knoa Pharma LLC
007488	Bachman, Jenny	Sr. Benefits and HRIS Specialist	Knoa Pharma LLC
007492	McElderry, Robert A	Executive Director Government Affairs	Knoa Pharma LLC
007699	Colinet, Yvanne	Associate Director Medical Affairs Operations and Compliance	Knoa Pharma LLC
007747	Denton, Jason R	Sr. QA Specialist II Batch Disposition	Knoa Pharma LLC
007794	Aleali, Roxana	VP General Counsel and Corporate Secretary	Knoa Pharma LLC
007849	Plaza, Manuel L	Team Lead Accounts Payable	Knoa Pharma LLC
007857	Grandison-Swaller, Amy L	Sr. Administrative Asc. II 2100208	Knoa Pharma LLC
007954	Crudele, Nancy T	Executive Director Medical Comm. & Strategy	Knoa Pharma LLC

007974	Slabicki, Susan M	Administrative Associate V 2251208	Knoa Pharma LLC
007975	Liesman, Esther	Associate Director Customer Service	Knoa Pharma LLC
008004	Cataldo, Marc J	Director Medical Communications & Strategy	Knoa Pharma LLC
008038	Mitchell, Nickie G	Quality Specialist III Doc Systems	Knoa Pharma LLC
008122	Rosen, David N	Head of Commercial Operations and Strategic Portfolio Management	Knoa Pharma LLC
010108	Morrissey, Thomas	Sr. Director eDiscovery & Legal Operations	Knoa Pharma LLC
010366	Feltz, Margaret K	VP Chief Compliance Officer	Knoa Pharma LLC
010467	Ewers, Laura K	Sr. Quality Specialist III Val & QA System	Knoa Pharma LLC
010769	Daniel, Sanil	Head of Corporate Procurement	Knoa Pharma LLC
010779	Eklund, Lisa E	Director QA NC Mfg and Development	Knoa Pharma LLC
010824	Leipold, Monica	Executive Director Strategic Projects & Business Initiatives	Knoa Pharma LLC
010825	Bauza, Luis N	Director Investigations and OSF Security	Knoa Pharma LLC
010844	Roldan, Carmen I	Sr. Analyst Ethics & Compliance	Knoa Pharma LLC
011298	Knight, Jeanne M	Sr. Credit Manager	Knoa Pharma LLC
011601	Ford, Regina W	Associate Director Quality 6958208	Knoa Pharma LLC
011782	Errigo, Demetrio P	Associate Director Infrastructure and Cloud Services	Knoa Pharma LLC
012062	Kharche, Swapnil	Associate Director Data Analytics and BI	Knoa Pharma LLC
012411	Biggs, Laura	Sr. Team Lead Customer Service	Knoa Pharma LLC
012524	Pastiva Kocot, Diane M	Buyer	Knoa Pharma LLC
012878	Major, Jennifer A	Sr. Pkg. Development Engineer	Knoa Pharma LLC
013349	Stinson, Neil T	Associate Director Pharm Tech Services	Knoa Pharma LLC
020227	Ronning, Michael T	VP Sales and Marketing	Knoa Pharma LLC
020233	Kacholakalayil, James T	Director Drug Safety Systems & Support	Knoa Pharma LLC
020392	Feldman, Nina R	IT Coordinator	Knoa Pharma LLC
020423	Stewart, Janet M	Customer Service Team Lead	Knoa Pharma LLC
020525	Webb, Danielle J	Sr. Manager Financial Planning & Analysis	Knoa Pharma LLC
020569	Kobi, Clifford W	Lead Scientist 4900208	Knoa Pharma LLC
020743	Baldridge, Stacy D	Executive Director Clinical Outreach & PHI Engagement 4755208	Knoa Pharma LLC
021574	Nair, Jaya	Sr. Scientist 4900208	Knoa Pharma LLC
021690	Hackney, Rebecca L	Sr. Manager Acctng. & Financial Reporting	Knoa Pharma LLC
021873	Brueski, Elaine K	Manager Government Program Operations	Knoa Pharma LLC
022588	Suthers, Colleen E	Associate Director IT Business Partner 2450208	Knoa Pharma LLC
022647	Beamon, Shaniqua D	Sr. Customer Service Rep	Knoa Pharma LLC
022864	Northington, Joseph W	VP Quality	Knoa Pharma LLC
023024	Zanetti, Amanda N	Manager Government Institutional Operations	Knoa Pharma LLC
023037	Gilbride, John P	Director Ethics & Compliance	Knoa Pharma LLC
023436	Erensen, Jennifer G	Executive Director Med. Affairs Strategic Research	Knoa Pharma LLC
023524	Charles, Donstan	Director Corporate Procurement and Strategic Sourcing	Knoa Pharma LLC
023833	Snow, Sheri L	Sr. Clinical Project Manager 4713208	Knoa Pharma LLC
024139	Eason, Bobby M	Lead Scientist 4900208	Knoa Pharma LLC
024222	Bizzell, Rikki L	Sr. Quality Specialist I Team Lead 2191208	Knoa Pharma LLC
024334	Takwa, Kimberly J	Director IT Governance and Validation Services	Knoa Pharma LLC
024435	McGuire, Donogh	VP Chief of Technical Operations	Knoa Pharma LLC
024465	Baker, Adrienne G	Associate Director Ethics & Compliance	Knoa Pharma LLC
024732	Hobbick, Christina E	Manager Pricing Compliance	Knoa Pharma LLC
024783	Brown, Scott W	Sr. Manager Regulatory Operations 4010208	Knoa Pharma LLC
025340	Tyagi, Neha	Associate Director IT Governance and Client Services	Knoa Pharma LLC
025400	Sunkara, Srinivasarao	Associate Director Mfg Supply Chain Systems Analysis & Support	Knoa Pharma LLC
025416	Yang, Weiying	Sr. Assistant General Counsel Patent and Product IP Strategy	Knoa Pharma LLC
025727	Inaparthy, David Paul	Director ERP Technical Delivery	Knoa Pharma LLC
026067	Probert, David A	Sr. Manager OS/DBA Infrastructure Services	Knoa Pharma LLC
026119	Harrington, Nella	Sr. Manager Regulatory Affairs 4010208	Knoa Pharma LLC
026283	Stancil, Amy J	Associate Director Quality 6958208	Knoa Pharma LLC
026284	Gregory, Tammie M	Manager Int'l Supply Chain Customs & Log	Knoa Pharma LLC
026338	Biggs, Lisa E	Quality Advisor	Knoa Pharma LLC
026563	Darvesh, Soofiyan H	Associate Director SAP Procurement/ HRIS	Knoa Pharma LLC
026720	Qin, Ling	Network Infrastructure Lead	Knoa Pharma LLC
026836	DeStefano, Christine M	Head of Total Rewards	Knoa Pharma LLC
026867	Pearson, Jeffry A	Sr. QA Specialist II Batch Disposition	Knoa Pharma LLC
026870	DeBiase, Francesca	Senior Finance Coordinator	Knoa Pharma LLC
027657	Alfieri, Thomas J	Director Medical Affairs Strategic Research	Knoa Pharma LLC
028070	Brown, Richard C	Associate Director Finance	Knoa Pharma LLC
028189	Krishnan, Devi	Sr. Analyst Managed Care Rebates and Data	Knoa Pharma LLC
028216	Koch, Bruce J	Chief Patent Counsel	Knoa Pharma LLC
028369	Saussy Jr, David L	Head of Business Dev.	Knoa Pharma LLC
028421	Cheng, Daniel	Associate Director Government Pricing	Knoa Pharma LLC
028488	Raina, Anupam	Director IT Business Relationship 6954208	Knoa Pharma LLC
028604	Shank, William R	Head of Market Access	Knoa Pharma LLC
028644	Cole, Vanessa	Executive Director CNS Marketing	Knoa Pharma LLC
028777	Rajmane, Anita S	Sr. Manager Regulatory Strategy 4010208	Knoa Pharma LLC
028922	Igo, David H	Executive Director Pharmaceutical and Analytical Development 4900208	Knoa Pharma LLC

028923	Draper, Sara L	Director Analytical Research and Development 4900208	Knoa Pharma LLC
028945	Reed, Chad H	Sr. Scientist 4900208	Knoa Pharma LLC
028949	Patz, Hillary L	Executive Director Organizational Effectiveness & Strategic HR Business Partnership	Knoa Pharma LLC
028963	Bricault, Elaine M	Manager Regulatory Affairs Product Labeling 4010208	Knoa Pharma LLC
028967	Pascale, Valentine J	Director Med. Communications & Strategy	Knoa Pharma LLC
029046	Hodges, Jason M	Director Market Research and Field Operations	Knoa Pharma LLC
029047	Ortiz, Ronnie	Director Pharmaceutics 4900208	Knoa Pharma LLC
029052	Upasani, Rashmi S	Director Regulatory Strategy 4010208	Knoa Pharma LLC
029064	Hardee, Aaron N	Sr. Quality Specialist I, GxP Deviations and CAPAs	Knoa Pharma LLC
029193	Pacicca, Elizabeth	Sr. Communications & CSR Coordinator	Knoa Pharma LLC
029222	Santana, Jasmine A	Sr. Quality Specialist II 6958208	Knoa Pharma LLC
029253	Bolton-Williams, Delaine	Associate Director Regulatory Affairs 4010208	Knoa Pharma LLC
029380	Ghnaimeh, Hussein	VP, Chief Information and Technology Officer	Knoa Pharma LLC
029460	Darragh, Keith J	EVP, Chief Financial Officer	Knoa Pharma LLC
029638	Ruta, Erin L	Manager Corporate Law	Knoa Pharma LLC
029655	Kesselman, Marc L	President & Chief Executive Officer	Knoa Pharma LLC
029714	Annunziata, Jennifer H	Assistant Controller	Knoa Pharma LLC
029768	Santonastaso, Michelle	Sr. Rebate Specialist B120208	Knoa Pharma LLC
029860	McIntyre, Meredith A	Sr. Talent Manager	Knoa Pharma LLC
029922	Epperlein, Sara K	Associate Director Talent Mgmnt. & Strategic HRBP	Knoa Pharma LLC
029923	McCarthy, Karen M	Asc. General Counsel Head of Corporate Law	Knoa Pharma LLC
030301	Ducharme, Julie	VP Chief Scientific Officer 4750208	Knoa Pharma LLC
030302	Negron, Monserrat	Credit Analyst	Knoa Pharma LLC
030390	Rohr, Zachary	Scientist 4900208	Knoa Pharma LLC
030419	Craig, Wayne H	Sr. Scientist 4900208	Knoa Pharma LLC
030483	Sharp, Michele	VP, Corporate Communications and Corporate Social Responsibility	Knoa Pharma LLC
030506	Chang, Crystal	Medical Science & Managed Care Liaison	Knoa Pharma LLC
030510	Eddy, Evangeline P	Associate Director Toxicology 4300208	Knoa Pharma LLC
030570	Russo, Karen	Manager, Intellectual Property Support	Knoa Pharma LLC
040005	Jack, Marsha	Director Finance and Treasury	Knoa Pharma LLC
040039	Daniel, Sajjan	VP Drug Safety & Pharmacovigilance	Knoa Pharma LLC
040215	Gari, Venkat G	Associate Medical Director DS	Knoa Pharma LLC
040260	Malempati, Manjeera	Executive Director, Safety Operations, Standards & Compliance	Knoa Pharma LLC
040398	Narulkar, Rohan	Sr. Manager Drug Safety Vendor Operations	Knoa Pharma LLC
040428	Lee, Jungeun	Director FP&A	Knoa Pharma LLC
040457	Alva, Pallavi A	Manager Drug Safety Systems	Knoa Pharma LLC
040531	Cho, Sulin	Sr. Asst. General Counsel Corporate Law	Knoa Pharma LLC
040540	Pratt, LaTonya W	Sr. Quality Specialist II SQA	Knoa Pharma LLC
040549	McDustrell, William G	Manager Supply Chain Operations 6959208	Knoa Pharma LLC
040580	Worley-Ham, Karla	Sr. Manager Regulatory Advertising and Promotional Review 4010208	Knoa Pharma LLC
040646	Cheatham, Cindy G	Quality Specialist I Doc Systems	Knoa Pharma LLC
040647	Kotharu, Pranavi	Sr. Analyst Validation	Knoa Pharma LLC
040732	Corallo, Karen	Asc. General Counsel Head of Regulatory Law	Knoa Pharma LLC
040782	Vaidian, Sonia	Associate Director Medical Safety	Knoa Pharma LLC
040850	Anand, Sanjeev	Executive Medical Director Medical Safety	Knoa Pharma LLC
040927	Jackson, Ke'Aundra	Scientist 4900208	Knoa Pharma LLC
040982	Woods, Kelly M	Administrative Associate V 6950208	Knoa Pharma LLC
041030	Masselli, Michael	Senior Accountant	Knoa Pharma LLC
041038	Rivera, Edward	Sr. Manager A/P & Disbursement	Knoa Pharma LLC
041092	Gajendira Babu, Subhiksha	Manager Suspicious Ordering Monitoring	Knoa Pharma LLC
041125	Puthiyath, Marlene M	Associate Director Legislative Alliance	Knoa Pharma LLC
041179	Frank, Anna	Medical Science Liaison	Knoa Pharma LLC
041192	Daly, John R	Sr. Manager Ethics & Compliance (SOM)	Knoa Pharma LLC
041272	Grasser, Lori	Sr. Analyst Government Pricing	Knoa Pharma LLC
041328	Matta, James B	Director Trade	Knoa Pharma LLC
041330	DeFrancesco, William V	Director Health Systems	Knoa Pharma LLC
041366	Han, Jonathan C	Sr. Manager R&D and Medical Affairs Finance	Knoa Pharma LLC
041374	Seenarraine, Jessica	Controller	Knoa Pharma LLC
041485	Fernandez Jr, Luis A	Manager Sourcing & Procurement, Direct Materials	Knoa Pharma LLC
041525	Rahaman, Rozeena Z	Sr. Associate A/P and Disbursements	Knoa Pharma LLC
041554	Foland, Tammy	Sr. Quality Specialist I, GxP Training	Knoa Pharma LLC
041566	Veley, Kristin	Director Risk Evaluation Mitigation Strategy (REMS)	Knoa Pharma LLC
041671	Girgis, Matthew M	Analyst Government Price Reporting	Knoa Pharma LLC
041836	Narron, Cassi	Sr. Quality Specialist I, GxP Training	Knoa Pharma LLC
041862	Hussain, Ferdous	Sr. Manager Government Program Compliance	Knoa Pharma LLC
041877	Frazier, Jared	Sr. QA Specialist II Batch Disposition	Knoa Pharma LLC
041895	Johnson, Adelah A	Sr. Quality Specialist II GCP/PV/Medical/Regulatory	Knoa Pharma LLC

Knoa Pharma LLC
201 Tresser Blvd
Stamford, CT 06901

Attachment H

List of Employees, Agents, Independent Contractors, etc. of the Applicant Statement

There are currently no "active" employees or contractors (or other external resources) of Knoa Pharma LLC. A complete list will be sent to Nevada once available.

Knoa Pharma LLC
201 Tresser Blvd
Stamford, CT 06901

Employee List*:
**As there are no "active" employees of Knoa Pharma LLC at this time, below is a list of Purdue Pharma L.P.'s employees. This list is subject to change and if updated, the revised list will be sent to Nevada once available.*

Employee Name	Position
Atherton, Michele E	Sr. Clinical Project Manager 4713208
Szetela, Andrew	Manager Administrative Services
Jimenez, Janet	Administrative Associate V 2200208
Visciglia, Sharon E	Sr. Credit Analyst
Sielert, William S	Director ERP Applications
Kusinski, Lynn E	Director Benefits HRIS & Payroll
Cipriano, Alessandra	Sr. Director Clinical Operations 4713208
Cabral, Deolinda S	Associate Director Payroll Services
Ostrowski, Christine A	Head of Pricing
Burko, Deborah A	Associate Director Clinical Project Management 4713208
Ramsey, Harry L	Sr. Manager Package Design & Development
Kraft, Eric	Principal Scientist 4900208
Evans, Susan K	Sr. Administrative Ast.
Graziano, Alicia C	Director Pricing Operations
Mohler, Niketa	Package Development Engineer
Beck-Sechow, Jennifer K	Sr. Manager Payroll Services
Iemma, Cristina D	Associate Director Drug Safety
Issa, Giselle N	Director Law Dept. Operations
Mitchell, Laura K	National Accounts Executive 8601208
Giordano, Jennifer L	Head of Business Operations
Vento, Anne D	Director R&D Quality Assurance
Kwarcinski, Monica A	VP Medical Affairs
Shet, Manjunath S	Sr. Director PKDM 4300208
Eastman, Lawrence M	Associate Director ISQA
Harris, Stephen C	Head of Clinical Pharmacology 4400208
Laurel, Karen A	VP Human Resources
Belward, Deborah	Administrative Associate III 4717208
Landau, Craig J	President & Chief Executive Officer
Boykin, Deborah C	Administrative Associate V 4750208
Ripa, Steven R	Executive Medical Director 4400208
Ahrenberg, Jennifer D	Sr. Quality Specialist III 2190208
Watson, Laura J	Director Customer Service
Foldeak-Edwards, Jean M	Administrative Associate IV 8800208
Meehan, Maureen	Contract Paralegal
Casinelli, Emily P	Legal Specialist

Knoa Pharma LLC
201 Tresser Blvd
Stamford, CT 06901

O'Grady, Diane	Manager Regulatory Affairs Product Labeling 4010208
Wargo, Dawn M	Sr. Customer Service Rep
Sessler, Nelson E	Director Clinical Development Lead 4400208
Zemble, Gerald L	Sr. Quality Specialist III SQA
Williams, Teresa P	Sr. QA Specialist I Batch Disposition
Sullivan, Brian	Director IT Business Relationship 2450208
Bhaskar, Sailaja B	VP Clinical R&D 4750208
Nelson, Jacqueline O	Director Regulatory Affairs 4010208
Gipson, Michael S	Sr. Quality Specialist III Auditing Team Lead
Christensen, Kris	Director Mkt Access Contracting & Analytics 8800208
Hedgepeth, Shelton M	Sr. QA Specialist I Batch Disposition
Lauriat, Jennifer D	Manager Corporate Procurement
Taylor, Tonia T	Sr. Quality Specialist II
Shah, Rupa P	National Director Medical Science Liaisons
Ricarte, Maria C	Asc. General Counsel Head of Lit. Risk Mgmt
Sparta, Gregory V	Executive Director Regulatory Affairs 4010208
Dhaliwal, Kulwant	Associate Director Sales & Distribution Systems Analysis & Support
Geremia, Cynthia A	Director Information Research & Management
Whiteside, Garth T	Head of Pre-Clinical Development 4300208
Gandhi, Mukeshkumar T	Sr. Quality Specialist III QA Improvement 2192208
MacDonald, Colleen M	Manager Law Department Technical Systems & Data
Vo, Luong V	Sr. Quality Specialist III GCP/PV/REMS
Haase Jr, Kurt E	Director Infrastructure & Collaboration Svc
Johnson, Alan D	Sr. Quality Advisor SQA Team Lead
Bartolo, Donna M	Sr. Administrative Asc. I 2200208
Reilly, Kevin G	Sr. Scientist 4900208
Sisto, Laura	Sr. Packaging Design Specialist
Mercer, Jeremy M	Sr. Quality Specialist III 2190208
Bachman, Jenny	Sr. Benefits and HRIS Specialist
McElderry, Robert A	Executive Director Government Affairs
Colinet, Yvanne	Associate Director Medical Affairs Operations and Compliance
Denton, Jason R	Sr. QA Specialist II Batch Disposition
Aleali, Roxana	VP General Counsel and Corporate Secretary
Plaza, Manuel L	Team Lead Accounts Payable
Grandison-Swaller, Amy L	Sr. Administrative Asc. II 2100208
Crudele, Nancy T	Executive Director Medical Comm. & Strategy
Slabicki, Susan M	Administrative Associate V 2251208
Cataldo, Marc J	Director Medical Communications & Strategy
Mitchell, Nickie G	Quality Specialist III Doc Systems

Knoa Pharma LLC
201 Tresser Blvd
Stamford, CT 06901

Rosen, David N	Head of Commercial Operations and Strategic Portfolio Management
Morrissey, Thomas	Sr. Director eDiscovery & Legal Operations
Feltz, Margaret K	VP Chief Compliance Officer
Ewers, Laura K	Sr. Quality Specialist III Val & QA System
Daniel, Sanil	Head of Corporate Procurement
Eklund, Lisa E	Director QA NC Mfg and Development
Leipold, Monica	Executive Director Strategic Projects & Business Initiatives
Bauza, Luis N	Director Investigations and OSF Security
Roldan, Carmen I	Sr. Analyst Ethics & Compliance
Knight, Jeanne M	Credit Manager
Ford, Regina W	Associate Director Quality 6958208
Errigo, Demetrio P	Associate Director Infrastructure and Cloud Services
Kharche, Swapnil	Associate Director Data Analytics and BI
Biggs, Laura	Sr. Team Lead Customer Service
Pastiva Kocot, Diane M	Buyer
Major, Jennifer A	Sr. Pkg. Development Engineer
Stinson, Neil T	Associate Director Pharm Tech Services
Ronning, Michael T	VP Sales/Mktg &GenMgr Adlon Therapeutics
Kacholakalayil, James T	Director Drug Safety Systems & Support
Feldman, Nina R	IT Coordinator
Stewart, Janet M	Customer Service Team Lead
Webb, Danielle J	Sr. Manager Financial Planning & Analysis
Kobi, Clifford W	Lead Scientist 4900208
Baldridge, Stacy D	Executive Director Clinical Outreach & PHI Engagement 4755208
Nair, Jaya	Sr. Scientist 4900208
Hackney, Rebecca L	Sr. Manager Acctng. & Financial Reporting
Brueski, Elaine K	Manager Government Program Operations
Suthers, Colleen E	Associate Director IT Business Partner 2450208
Beamon, Shaniqua D	Sr. Customer Service Rep
Northington, Joseph W	VP Quality
Zanetti, Amanda N	Manager Government Institutional Operations
Gilbride, John P	Director Ethics & Compliance
Erensen, Jennifer G	Executive Director Med. Affairs Strategic Research
Charles, Donstan	Associate Director Corporate Procurement
Snow, Sheri L	Sr. Clinical Project Manager 4713208
Eason, Bobby M	Lead Scientist 4900208
Bizzell, Rikki L	Sr. Quality Specialist I Team Lead 2191208
Takwa, Kimberly J	Director IT Governance and Validation Services
McGuire, Donogh	VP Chief of Technical Operations

Knoa Pharma LLC
201 Tresser Blvd
Stamford, CT 06901

Baker, Adrienne G	Associate Director Ethics & Compliance
Hobbick, Christina E	Manager Pricing Compliance
Brown, Scott W	Sr. Manager Regulatory Operations 4010208
Tyagi, Neha	Associate Director IT Governance and Client Services
Sunkara, Srinivasarao	Associate Director Mfg Supply Chain Systems Analysis & Support
Yang, Weiying	Sr. Assistant General Counsel Patent and Product IP Strategy
Inaparthy, David Paul	Director ERP Technical Delivery
Probert, David A	Sr. Manager OS/DBA Infrastructure Services
Harrington, Nelia	Sr. Manager Regulatory Affairs 4010208
Stancil, Amy J	Sr. Manager QA Batch Release
Gregory, Tammie M	Manager Int'l Supply Chain Customs & Log
Biggs, Lisa E	Quality Advisor
Darvesh, Soofiyan H	Associate Director SAP Procurement/ HRIS
Qin, Ling	Network Infrastructure Lead
DeStefano, Christine M	Head of Total Rewards
Pearson, Jeffry A	Sr. QA Specialist II Batch Disposition
DeBiase, Francesca	Senior Finance Coordinator
Alfieri, Thomas J	Director Medical Affairs Strategic Research
Brown, Richard C	Associate Director Finance
Krishnan, Devi	Sr. Analyst Managed Care Rebates and Data
Koch, Bruce J	Chief Patent Counsel
Saussy Jr, David L	Head of Business Dev.
Cheng, Daniel	Sr. Manager Government Pricing
Raina, Anupam	Director IT Business Relationship 6954208
Shank, William R	Head of Market Access
Cole, Vanessa	Executive Director CNS Marketing
Rajmane, Anita S	Sr. Manager Regulatory Strategy 4010208
Igo, David H	Executive Director Pharmaceutical and Analytical Development 4900208
Draper, Sara L	Director Analytical Research and Development 4900208
Patz, Hillary L	Executive Director Organizational Effectiveness & Strategic HR Business Partnership
Bricault, Elaine M	Manager Regulatory Affairs Product Labeling 4010208
Pascale, Valentine J	Director Med. Communications & Strategy
Hodges, Jason M	Director Market Research and Field Operations
Ortiz, Ronnie	Director Pharmaceutics 4900208
Upasani, Rashmi S	Director Regulatory Strategy 4010208
Hardee, Aaron N	Sr. Quality Specialist I, GxP Deviations and CAPAs
Pacicca, Elizabeth	Sr. Communications & CSR Coordinator
Santana, Jasmine A	Sr. Quality Specialist II 6958208

Knoa Pharma LLC
201 Tresser Blvd
Stamford, CT 06901

Bolton-Williams, Delaine	Associate Director Regulatory Affairs 4010208
Ghnaimeh, Hussein	VP, Chief Information and Technology Officer
Darragh, Keith J	EVP, Chief Financial Officer
Ruta, Erin L	Manager Corporate Law
Kesselman, Marc L	Chief Legal Officer, EVP Strategy & Corp. Affairs
Annunziata, Jennifer H	Manager Accounting Services
Santonastaso, Michelle	Sr. Rebate Specialist 8120208
McIntyre, Meredith A	Sr. Talent Manager
Epperlein, Sara K	Associate Director Talent Mgmnt. & Strategic HRBP
McCarthy, Karen M	Asc. General Counsel Head of Corporate Law
Ducharme, Julie	VP Chief Scientific Officer 4750208
Negron, Monserrat	Credit Analyst
Rohr, Zachary	Scientist 4900208
Craig, Wayne H	Sr. Scientist 4900208
Sharp, Michele	VP, Corporate Communications and Corporate Social Responsibility
Chang, Crystal	Medical Science & Managed Care Liaison
Eddy, Evangeline P	Associate Director Toxicology 4300208
Russo, Karen	Manager, Intellectual Property Support
Pratt, Malcolm C	Sr. Quality Specialist II Quality Systems
Jack, Marsha	Director Finance and Treasury
Daniel, Sajjan	VP Drug Safety & Pharmacovigilance
Brahmia, Farah	Associate Director Ethics & Compliance
Gari, Venkat G	Associate Medical Director DS
Malempati, Manjeera	Executive Director, Safety Operations, Standards & Compliance
Narulkar, Rohan	Sr. Manager Drug Safety Vendor Operations
Lee, Jungeun	Associate Director R&D and Medical Affairs Finance
Alva, Pallavi A	Manager Drug Safety Systems
Cho, SuJin	Asst. General Counsel Corporate Law
Pratt, LaTonya W	Sr. Quality Specialist II SQA
McDustrell, William G	Manager Supply Chain Operations 6959208
Alonso Succar, Juan Diego	Director Ethics & Compliance
Worley-Ham, Karla	Sr. Manager Regulatory Advertising and Promotional Review 4010208
Cheatham, Cindy G	Quality Specialist I Doc Systems
Kotharu, Pranavi	Sr. Analyst Validation
Corallo, Karen	Asc. General Counsel Head of Regulatory Law
Vaidian, Sonia	Associate Director Medical Safety
Anand, Sanjeev	Executive Medical Director Medical Safety
Jackson, Ke'Aundra	Scientist 4900208

Woods, Kelly M	Administrative Associate V 6950208
Masselli, Michael	Senior Accountant
Rivera, Edward	Sr. Manager A/P & Disbursement
Gajendira Babu, Subhiksha	Manager Suspicious Ordering Monitoring
Puthiyath, Marlene M	Associate Director Legislative Alliance
Frank, Anna	Medical Science Liaison
Daly, John R	Sr. Manager Ethics & Compliance (SOM)
Grasser, Lori	Sr. Analyst Government Pricing
Matta, James B	Director Trade
DeFrancesco, William V	Director Health Systems
Han, Jonathan C	Manager R&D and Medical Affairs Finance
Seenarraine, Jessica	Controller
Fernandez Jr, Luis A	Manager Sourcing & Procurement, Direct Materials
Rahaman, Rozeena Z	Sr. Associate A/P and Disbursements
Foland, Tammy	Sr. Quality Specialist I, GxP Training
Girgis, Matthew M	Analyst Government Price Reporting
Narron, Cassi	Sr. Quality Specialist I, GxP Training

Agents or independent contractors, consultants, guardians or personal representatives.
**As there are no "active" contractors of Knoa Pharma LLC at this time, below is a list of Purdue Pharma L.P.'s external resources. This list is subject to change and if updated, the revised list will be sent to Nevada once available.*

External Resource Name	Agency
Hart, Angela M	Achsah, LLC
Munoz, Ruben	Alix Partners
Engelhard, Alex	Alix Partners
Ross, Bella	Alix Partners
Henkel, Bryce	Alix Partners
Nguyen, Lan	Alix Partners
Gong, Limi	Alix Partners
DelConte, Jesse	Alix Partners
Donahue, Lisa	Alix Partners
DePalma, Andrew	Alix Partners
Collura, Richard	Alix Partners
Bhattal, HS	Alix Partners
Shen, Clarice	Alix Partners
Kanazireva, Emilia	Alix Partners
Chien, Nathan	Alix Partners
Betik, Suzie	Alix Partners
Rapoport, Jared	Alix Partners

Stamm, Ryan	All Star Software Systems
Kundrath, Joe	All Star Software Systems
Sutfin, Deb	All Star Software Systems
Sagendorf, Scott	All Star Software Systems
Kaminsky, Kim	All Star Software Systems
Benincaso, Diana	All Star Software Systems
Ramnath, Arvind	Anju Software
Ahmed, Shaik	Clogration LLC
Ranganathan, Jagadeeswwaran	Clogration LLC
Pavan, Venkata	Clogration LLC
Abdul, Muyeed	Clogration LLC
Puligouni, Reddeppa	Clogration LLC
Addagoodi, Dilip	Cognizant Technology Solutions
V, Upendra	Cognizant Technology Solutions
Thakur, Sai Ram Singh	Cognizant Technology Solutions
Chawla, Saurabh	Cognizant Technology Solutions
Pasca, Pablo	Cognizant Technology Solutions
Thangavel, Jagadeesan	Cognizant Technology Solutions
Maria, Indira	Cognizant Technology Solutions
Thondapu, Manoj	Cognizant Technology Solutions
Walunj, Ganesh	Cognizant Technology Solutions
M, Sowmiya	Cognizant Technology Solutions
Prabhu, Raja	Cognizant Technology Solutions
Sunku, Vijaya	Cognizant Technology Solutions
Kodela, Ravi	Cognizant Technology Solutions
Ijaz, Ahmed	Cognizant Technology Solutions
Anumandla, Monishkumar	Cognizant Technology Solutions
Anandappa, KiranKumar	Cognizant Technology Solutions

Karumuru, VijayaSankar	Cognizant Technology Solutions
Easo, Saju	Cognizant Technology Solutions
Saminathan, Arivazhagan	Cognizant Technology Solutions
Ahmed, Abdulkerim	Cognizant Technology Solutions
Kumbhar, Sagar	Cognizant Technology Solutions
Parab, Priyank	Cognizant Technology Solutions
B, Kathiravan	Cognizant Technology Solutions
Dutta, Soumen	Cognizant Technology Solutions
Murthy, Ramachandra	Cognizant Technology Solutions
Narasappa Naidu, Godi	Cognizant Technology Solutions
Pothampalli, Archana	Cognizant Technology Solutions
Cherqi, Driss	Cognizant Technology Solutions
Mahanthi, Vasavi	Cognizant Technology Solutions
Chennupati, NavyaSri	Cognizant Technology Solutions
Ganesh, Sankar	Cognizant Technology Solutions
Zadbuke, Rahul	Cognizant Technology Solutions
Patel, Deepak	Cognizant Technology Solutions
Gajera, Dhaval	Cognizant Technology Solutions
Thota, Avinash	Cognizant Technology Solutions
Pandey, Shalabh	Cognizant Technology Solutions
Chopdar, Shantadeepa	Cognizant Technology Solutions
Avhad, Monika	Cognizant Technology Solutions

Pandya, Shraddha	Cognizant Technology Solutions
Mortha, Shailaja	Cognizant Technology Solutions
Choudhary, Vikram	Cognizant Technology Solutions
Chauhan, Aditi	Cognizant Technology Solutions
Bobade, Anand	Cognizant Technology Solutions
Kale, Vaibhavi	Cognizant Technology Solutions
Patel, Ronak	Cognizant Technology Solutions
Agre, Suvarna	Cognizant Technology Solutions
Singh, Jatinder	Cognizant Technology Solutions
Bhalerao, Sunil	Cognizant Technology Solutions
Das, Amrita	Cognizant Technology Solutions
Patil, Vaibhav	Cognizant Technology Solutions
Amode, Neha	Cognizant Technology Solutions
Amrut Suryawanshi, Kalpesh	Cognizant Technology Solutions
Wethekar, Vijay	Cognizant Technology Solutions
Menon, Sneha	Cognizant Technology Solutions
Mutum, Sonia	Cognizant Technology Solutions
Gupta, Ankush	Cognizant Technology Solutions
Jain, Rohit	Cognizant Technology Solutions
Savaliya, Shital	Cognizant Technology Solutions
Dangat, Pradnya	Cognizant Technology Solutions
Gawand, Komal Suresh	Cognizant Technology Solutions

Bhukya, Thirupathi	Cognizant Technology Solutions
Sai Prathyusha, Vemireddy	Cognizant Technology Solutions
Vijay Kumar, S.N.	Cognizant Technology Solutions
Matkar, Santosh	Cognizant Technology Solutions
Gulhane, Mayuri Ravindra	Cognizant Technology Solutions
Patil, Shweta	Cognizant Technology Solutions
Phalke, Akshada	Cognizant Technology Solutions
Jain, Geetanjali	Cognizant Technology Solutions
Menon, Sriraj	Cognizant Technology Solutions
Loorthusamy, Gnanaprakash	Cognizant Technology Solutions
Villanueva, Sharmaine	Cognizant Technology Solutions
Maclennan, Diane	Cognizant Technology Solutions
Gamboa De Leon, Pinky	Cognizant Technology Solutions
Esmero, Keith	Cognizant Technology Solutions
Ballado, Jeovanie	Cognizant Technology Solutions
De La Cruz, Jovelyn	Cognizant Technology Solutions
Sanjay Yeole, Sarvesh	Cognizant Technology Solutions
Rajendra Gite, Priyanka	Cognizant Technology Solutions
Ghorpade, Vaishali	Cognizant Technology Solutions
Kaminetzky, Ben	Davis Polk
Lele, Ajay	Davis Polk
Kim, Andrew	DXC
Liao, Simon	DXC
Kim, Haejin	DXC
Wan, Leslie	DXC
Oh, Marie	DXC

Wang, Xuezhe	Genesis Research
Abril, Geovanny	Hexaware Technologies
Emekoba, Fortune	Hexaware Technologies
M, MARIA GUADALUPE	Hexaware Technologies
PEREZ LOPEZ, DAVID	Hexaware Technologies
Gadgil, Nimish Gadgil	Hexaware Technologies
Mohammod, Sameer Sarang	Hexaware Technologies
Ranjan, Shiv	Hexaware Technologies
Subramani, Bhaskaran	Hexaware Technologies
Gaware, Ganesh	Hexaware Technologies
Chawla, Gaurav	Hexaware Technologies
KETHA, VENKAT PRASAD	Hexaware Technologies
Vail, John	Hexaware Technologies
B, Raja	Hexaware Technologies
John, Isac	Hexaware Technologies
Recharla, Umesh Chandra Prasad	Hexaware Technologies
Singh, Prabal Pratap	Hexaware Technologies
Ramu, Sathish	Hexaware Technologies
Kamble, Swarup	Hexaware Technologies
R, Ranjith	Hexaware Technologies
Gaikward, Pradip Vittal	Hexaware Technologies
Saraswat, Akshat	Hexaware Technologies
Muthu, Yoganathan	Hexaware Technologies
Kumar, Amit	Hexaware Technologies
Kumar, Mohit	Hexaware Technologies
Grover, Chirag	Hexaware Technologies
Singh, Karan	Hexaware Technologies
Phaneendra, Rohith	Hexaware Technologies
Gupta, Nunna Subramanyam	Hexaware Technologies
Gayathri, Kamadi Divya	Hexaware Technologies
Balhara, Sandeep	Hexaware Technologies
Arumugam, Aswin	Hexaware Technologies
Selvan, Karthik	Hexaware Technologies
Hernandez, Raul	Hexaware Technologies
N, Muniraju	Hexaware Technologies
Venkatesan, Rukesh	Hexaware Technologies
TR, RajeshKumar	Hexaware Technologies
Jadli, Neha	Hexaware Technologies
Kumarij, Priyanka	Hexaware Technologies
Jothiramaling, Sridharan	Hexaware Technologies

P, Tamilarasan	Hexaware Technologies
Teerdhala, Rajesh	Hexaware Technologies
Luna, Essau	Hexaware Technologies
Peddi Reddy Gari, Purushotham Reddy	Hexaware Technologies
Villasana, Marco	Hexaware Technologies
Arevalo, Brenda	Hexaware Technologies
Ilanthamilan, Elanjezhiyan	Hexaware Technologies
Jackson, Lamont	Hexaware Technologies
Collier, Serdonnafer	Hexaware Technologies
Raja, Bharani	Hexaware Technologies
M P, Sajith	Hexaware Technologies
Pandey, Prabhat	Hexaware Technologies
Bhatt, Ankit	Hexaware Technologies
Kanojia, Chandan	Hexaware Technologies
Krishnakumar, Manikandan	Hexaware Technologies
T, Velu	Hexaware Technologies
Usman Irfan, Khan Muhammad	Hexaware Technologies
Dawange, Shubham Vinayak	Hexaware Technologies
Kurde, Nagesh Bharat	Hexaware Technologies
Naqvi, Ali	Hexaware Technologies
VC, Pooja	Hexaware Technologies
M, Asokan	Hexaware Technologies
T, Kala	Hexaware Technologies
Ramasamy, Ilangumani	Hexaware Technologies
Kandasamy, Rajesh	Hexaware Technologies
S, Sivaram	Hexaware Technologies
Patil, Ajinkya Bajirao	Hexaware Technologies
Anand, Namit	Hexaware Technologies
Anil, Akhil P	Hexaware Technologies
Janardhan Sav, Nitin	Hexaware Technologies
Chowdhury, Bikram	Hexaware Technologies
Ashok Reddy, Palla	Hexaware Technologies
Perumalla, Ramcharan	Hexaware Technologies
Dominic, Alex	Hexaware Technologies
Dhayallan, Eazhil	Hexaware Technologies
Gregory, Luke	Hexaware Technologies
Dubey, Archana	Hexaware Technologies
M, Devidas	Hexaware Technologies
R, Anand	Hexaware Technologies
J, Subhashita	Hexaware Technologies

Raj, Amit	Hexaware Technologies
Nair, Sudhil	Hexaware Technologies
Ezhilarasu, Adarsh	Hexaware Technologies
Manazir Husain, Rizvi Mohammad	Hexaware Technologies
Bhatia, Jasvinder	Hexaware Technologies
BG, Swaminathan	Hexaware Technologies
Mishra, Anmol	Hexaware Technologies
Maheshwari, Swapnil	Hexaware Technologies
G, Subramanian	Hexaware Technologies
Venkat Akula, Rahul Ranga	Hexaware Technologies
Khare, Anshay	Hexaware Technologies
Padhy, Ayush	Hexaware Technologies
Mohiuddin Sarfaraj Sayyad, Mohammad gulam	Hexaware Technologies
Pal, Aarti	Hexaware Technologies
Ubendran, Jayalakshmi	Hexaware Technologies
Guduri, Gowtham	Hexaware Technologies
Asbill, Ginger	Integreon
Van Dam, Ronald	King & Spaulding
Castillo, Oscar J	Magnit Global
Marshall, Tyhesha	Magnit Global
Hyland, Juli	Magnit Global
Tiruvuru, Rekha	Magnit Global
Mandala, Aparna	Magnit Global
Kannan, Likhitha	Magnit Global
Pathuri, Vani	Magnit Global
Kaverigari, Koushiki	Magnit Global
Veley, Kristin	Magnit Global
Adams, John	McGuire Woods LLP
Stacey, Paul	NTT DATA Business Solutions Inc.
Tiedeman, Ty	NTT DATA Business Solutions Inc.
Locker, Paul	NTT DATA Business Solutions Inc.
Ahmed, Sohail	NTT DATA Business Solutions Inc.
Bodanapu, Yuvaraju	NTT DATA Business Solutions Inc.
J, Sangeeta	NTT DATA Business Solutions Inc.

Uppara, Sreenivasulu	NTT DATA Business Solutions Inc.
Mohammed, Yusuf	NTT DATA Business Solutions Inc.
Gouram, Sai Bhargava Reddy	NTT DATA Business Solutions Inc.
Soni, Vivek	NTT DATA Business Solutions Inc.
Singh, Harsh Pratap	NTT DATA Business Solutions Inc.
Dokire, Raju	NTT DATA Business Solutions Inc.
Gade, Kiran Kumar	NTT DATA Business Solutions Inc.
Rendeddula, Chandra Sekhar Reddy	NTT DATA Business Solutions Inc.
Kathi, Sudheer Reddy	NTT DATA Business Solutions Inc.
Kumpatla, Kondababu	NTT DATA Business Solutions Inc.
Jena, Hejalin	NTT DATA Business Solutions Inc.
Nemani, Raghu	NTT DATA Business Solutions Inc.
Sunkara, Mohith Vardhan	NTT DATA Business Solutions Inc.
Gulla, Swaroop	NTT DATA Business Solutions Inc.
Pullepu, Aditya	NTT DATA Business Solutions Inc.
Gubbala, Taruna Usha	NTT DATA Business Solutions Inc.
Easterling, Jackie	NTT DATA Business Solutions Inc.
Ali, Danish	NTT DATA Business Solutions Inc.
Kumbhakarn, Rupesh	NTT DATA Business Solutions Inc.
Gopalsamy, Satheesh	NTT DATA Business Solutions Inc.
Tervoort, Djerry	NTT DATA Business Solutions Inc.
Surthi, Tejasri	NTT DATA Business Solutions Inc.

Mutyam, Sodasani	NTT DATA Business Solutions Inc.
Varma, Gottumukkala	NTT DATA Business Solutions Inc.
Panda, Prabas	NTT DATA Business Solutions Inc.
Addala, Laxmi	NTT DATA Business Solutions Inc.
Vinnakota, Shreya	NTT DATA Business Solutions Inc.
Jadhav, Dhanashree	NTT DATA Business Solutions Inc.
Nask, Susmit	NTT DATA Business Solutions Inc.
Burger, Ronald	NTT DATA Business Solutions Inc.
Hemalatha, Gujuka	NTT DATA Business Solutions Inc.
Patel, Samina	NTT DATA Business Solutions Inc.
Hassan, Mohammed	NTT DATA Business Solutions Inc.
Mazumder, Megha	NTT DATA Business Solutions Inc.
Ibhir, Ahmed	NTT DATA Business Solutions Inc.
Butler, Jenny	NTT DATA Business Solutions Inc.
Byreddy, Surya	NTT DATA Business Solutions Inc.
Gundavarapu, Ravikanth	NTT DATA Business Solutions Inc.
Biapureddy, Praveen	NTT DATA Business Solutions Inc.
Streit, Emery	NTT DATA Business Solutions Inc.
Carlisle, Nyla	NTT DATA Business Solutions Inc.
Parida, Mukesh	NTT DATA Business Solutions Inc.
Gudimetla, Santosh	NTT DATA Business Solutions Inc.
Konamanchili, Prem Kumar	NTT DATA Business Solutions Inc.

Balusu, Sravani	NTT DATA Business Solutions Inc.
Komaragiri, Sree Dhathri	NTT DATA Business Solutions Inc.
Chillakanti, Vyshnavi	NTT DATA Business Solutions Inc.
Shaik, Imran	NTT DATA Business Solutions Inc.
Chalasani, Phanishree	NTT DATA Business Solutions Inc.
Kakarlapudi, Nikhil	NTT DATA Business Solutions Inc.
Cherukumalli, Prashanth	NTT DATA Business Solutions Inc.
V., Kumar	NTT DATA Business Solutions Inc.
Kumar, Santosh	NTT DATA Business Solutions Inc.
Matthews, Barry	NTT DATA Business Solutions Inc.
V, Arun	NTT DATA Business Solutions Inc.
Desjardins, Bev	NTT DATA Business Solutions Inc.
Dasu, Chiranjeevi	NTT DATA Business Solutions Inc.
Yeminedi, Ram	NTT DATA Business Solutions Inc.
Jettigundla, Naresh	NTT DATA Business Solutions Inc.
Sudhakar, Meda	NTT DATA Business Solutions Inc.
Anne, Vikram	NTT DATA Business Solutions Inc.
Panda, Susanta	NTT DATA Business Solutions Inc.
Palkar, Ajinkya Vikas	NTT DATA Business Solutions Inc.
Gundapu, NomuLakshmi	NTT DATA Business Solutions Inc.
Pelluru, Chandrasekhar	NTT DATA Business Solutions Inc.
Bourne, Tom	NTT DATA Business Solutions Inc.

Sanchez, Mario	NTT DATA Business Solutions Inc.
Niehaus, Vanessa	NTT DATA Business Solutions Inc.
Chetty, Mahesh	NTT DATA Business Solutions Inc.
Khelge, Shishir	NTT DATA Business Solutions Inc.
Karabalaev, Aidar	One Identity LLC
Owais, Syed	POMS Corporation
Ayers, Lindsey	Rocky Mtn Poison & Drug Center (RMPDC)
Chung, Sara	Rocky Mtn Poison & Drug Center (RMPDC)
Lindroos, Jennifer	Rocky Mtn Poison & Drug Center (RMPDC)
Adorjan, Katherine	Rocky Mtn Poison & Drug Center (RMPDC)
Yacoub, Jocelyn	Rocky Mtn Poison & Drug Center (RMPDC)
Parish, Randall	Rocky Mtn Poison & Drug Center (RMPDC)
Westhoff, Kimberly	Rocky Mtn Poison & Drug Center (RMPDC)
Gibson, Kimberly	Rocky Mtn Poison & Drug Center (RMPDC)
King, Chandra	Rocky Mtn Poison & Drug Center (RMPDC)
Giles, Joel	Rocky Mtn Poison & Drug Center (RMPDC)
Chua, Theresa	Rocky Mtn Poison & Drug Center (RMPDC)
Defibaugh, Laurel	Rocky Mtn Poison & Drug Center (RMPDC)
Furlong, John	SCT Software
Robinson, Tamara	SCT Software
Gandham, Naveen	SCT Software
Sawyer, Tom	SharePoint Only
Bullock, Steve	Steve Bullock
Wyche, Bre'Anna	The Medical Affairs Company (TMAC)
Demir, Rabia	UCONN
Accettullo, Jason	Zudy

Knoa Pharma LLC
201 Tresser Blvd
Stamford, CT 06901

Lender or holder of indebtedness of the applicant: None

13B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☑ Ownership Change* ☑ Name Change* Anticipated May 1, 2026 See Attachment A ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 02443	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Knoa Pharmaceuticals LLC

Physical Address: 4701 International Boulevard W

City: Wilson State: NC Zip: 27893

Mailing Address (if different from physical address): same as above

City: State: Zip:

Telephone: 252-265-1900 Website: www.knoapharma.com

Name of Designated Representative (DR): Donogh M. McGuire

Licensing Company Email: wilson.applications@pharma.com DR Email: Donogh.mcguire@pharma.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☑ Dangerous Drugs	☑ Manufacturer
☐ Practitioners	☑ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Distributors and Repackagers		☐ Others:

Section 2: History of Company — See Attachment A	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Y

Attachment A

Statement Regarding Bankruptcy Emergence and Certain Disciplinary Actions

THE ANTICIPATED CHANGE OF CONTROL IS EXPECTED TO BE EFFECTIVE AS OF **MAY 1, 2026**, AS FURTHER DESCRIBED BELOW.

The answers provided in this application (including with respect to disciplinary matters) are expected to be true as of the date of effectiveness of the license requested. In addition, we provide the following in the interest of clarity.

On November 18, 2025, a plan of reorganization (the "Plan") was approved in the bankruptcy cases of Purdue Pharma LP ("PPLP") and its affiliates that are pending under the caption *In re Purdue Pharma L.P. et al.*, Case No. 19-23649 (SHL) (Bnkr. S.D.N.Y.) (the "Chapter 11 Cases"). Pursuant to the Plan, PPLP will not emerge from bankruptcy. Instead, substantially all of the assets of PPLP (including ownership of its current direct and indirect subsidiaries) will be transferred to Knoa Pharma LLC ("KPLLC"), a new entity that was formed to receive these assets. KPLLC, in turn, will be wholly owned by a 501(c)(4) non-profit foundation that will be formed prior to KPLLC's emergence from bankruptcy. As a result of the Plan's implementation, all of PPLP's current direct and indirect subsidiaries will become wholly owned by KPLLC, undergo a conversion to limited liability companies, and the subsidiary currently known as Purdue Pharmaceuticals L.P. will change its name to Knoa Pharmaceuticals LLC. The details of these changes are illustrated in diagrams on the succeeding pages.

KPLLC and its subsidiaries, including Knoa Pharmaceuticals LLC and Rhodes Pharmaceuticals LLC, will have no affiliation with PPLP following implementation of the Plan. However, in the interest of transparency we note:

1. On October 21, 2020, PPLP entered a plea agreement with the United States Department of Justice ("DOJ") to resolve DOJ's criminal and civil investigations of PPLP.[1] Pursuant to the PPLP Plea Agreement, on November 24, 2020, PPLP pled guilty before the U.S. District Court for the District of New Jersey (the "NJ District Court") to three felony counts to resolve all potential criminal charges against PPLP and its subsidiaries and affiliates with respect to the production, sale, marketing and distribution of opioid products between May 2007 and the present. Neither KPLLC nor any of PPLP's subsidiaries were charged with any violations of law and none are parties to PPLP's resolution with the DOJ.

   Under the terms of the PPLP Plea Agreement, PPLP is expected to be sentenced approximately seven days before the Plan becomes effective, which is currently anticipated

[1] The Plea Agreement and Civil Settlement Agreement comprising the proposed resolution are available at https://www.justice.gov/opa/press-release/file/1329576/download.

to occur on or around May 1, 2026. A judgment of conviction will follow after PPLP's sentencing hearing is concluded.[2]

2. Pursuant to the Chapter 11 Cases, a preliminary injunction is in effect that, among other things, enjoins proceedings relating to PPLP's prescription opioid business (including any actions brought by a governmental agency) that were or could have been commenced prior to the Chapter 11 Cases have been enjoined (the "Preliminary Injunction").

   Notwithstanding the foregoing, in April 2023, the State of Ohio Board of Pharmacy ("Ohio BOP") notified PPLP of a proposed disciplinary action ("Ohio Notice"), which alleges substantially similar facts or causes of action as those alleged in proceedings that are already subject to the Preliminary Injunction. Accordingly, we believe the Ohio Notice is enjoined by the Preliminary Injunction and does not constitute a pending action. Even if this is not the case, the Ohio Notice has no basis because it relies solely on PPLP's guilty plea which, pursuant to the PPLP Plea Agreement and as discussed in footnote 2 above, may be withdrawn prior to sentencing.

[2] While PPLP's guilty plea has been accepted by the NJ District Court, the PPLP Plea Agreement permits PPLP to withdraw its guilty plea in certain circumstances. Of remaining relevance, these include if: (1) the U.S. Department of Health and Human Services Office of Inspector General exercises, or states an intent to exercise, any available authority to exclude KPLLC from participation in federal healthcare programs; or (2) at sentencing, the NJ District Court rejects the Plea Agreement and the agreed disposition.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attachment B

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company (LLC)

State of Incorporation/Organization: Delaware (LLC) 3a of 7

Parent Company (if any): Knoa Pharma LLC

Corporation/Organization Name: Knoa Pharmaceuticals LLC

Mailing Address: 4701 International Boulevard W

City: Wilson State: NC Zip: 27893

Telephone: 252-265-1900 Email: wilson.applications@pharma.com

Contact Person Name: Donogh M. McGuire

Section 6: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration See Attachment C 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment D		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment E	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment A		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment F	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - See Attachment A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** See Attachment H	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment I	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment J	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ N/A	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). N/A	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8) N/A				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Knoa Pharmaceuticals LLC

Facility Name

Donogh M. McGuire

Print Name of Authorized Person Submitting Application

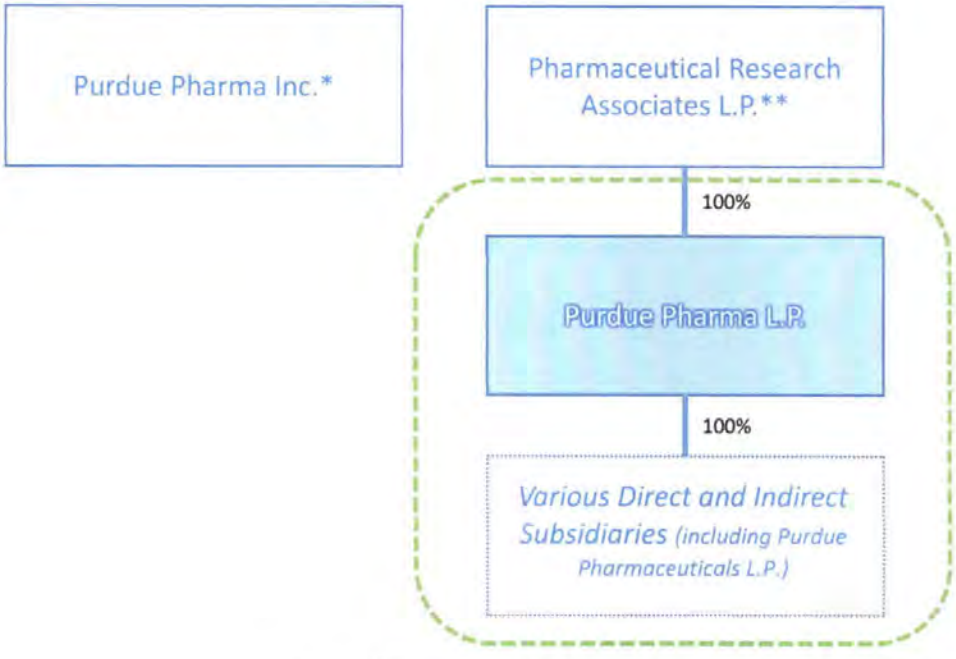
Original signature of Authorized Person (copies or stamps not accepted)

04/20/2026

Date

Board Use Only	Date Received: 4/27/26	Amount: $1000cc

Pre-Emergence Structure

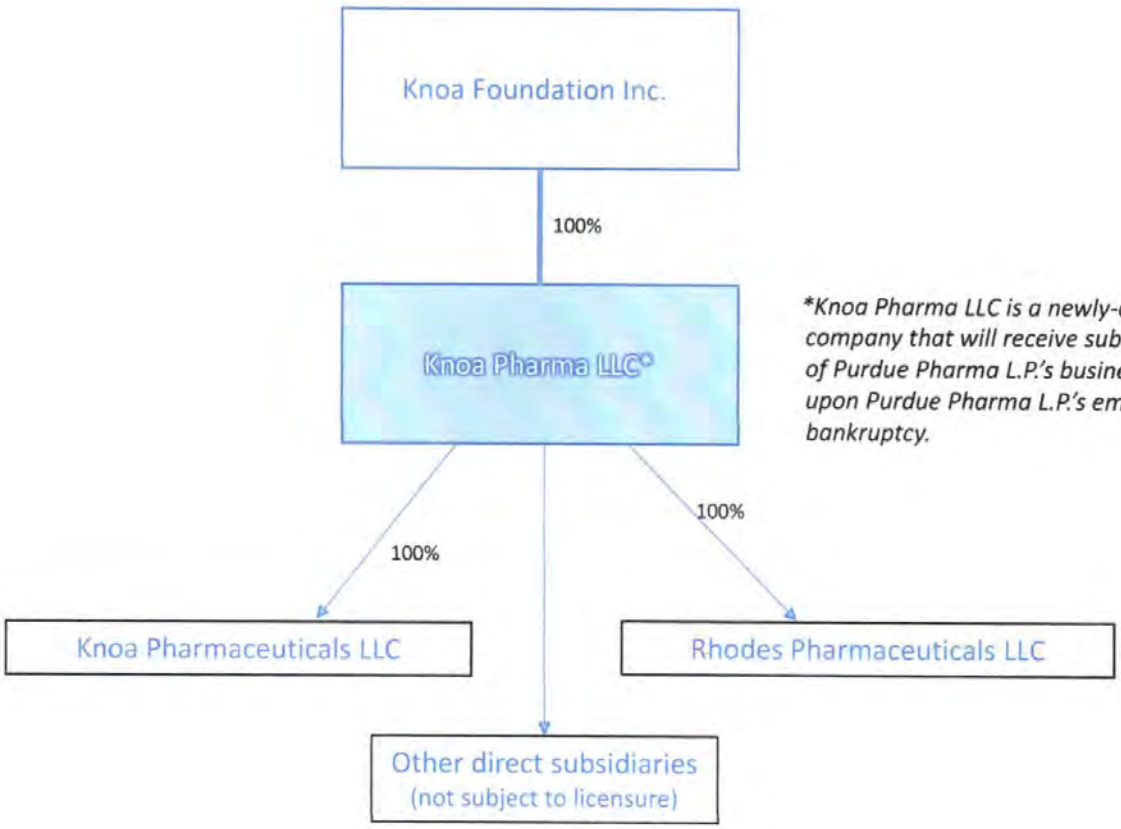


* *Purdue Pharma Inc. is the general partner of each entity inside of the dashed green border but has no equity interest in such entities.*

** *The ultimate owners of Pharmaceutical Research Associates L.P. are trusts 50 percent for the benefit of the family of Mortimer Sackler and 50 percent for the benefit of the family of Raymond Sackler.*

KLLCW2

Post-Emergence Structure



*Knoa Pharma LLC is a newly-created company that will receive substantially all of Purdue Pharma L.P.'s business and assets upon Purdue Pharma L.P.'s emergence from bankruptcy.

KLLCW2

Attachment B

Description of Operations

Knoa Pharmaceuticals LLC (the "Facility"), is a manufacturer and distributor of prescription drugs for human use in compliance with current good manufacturing standards.

The Facility manufactures and/or distributes products on behalf of the following affiliated companies ("Applicant Affiliates"):

- Purdue Pharma L.P. (to be replaced by Knoa Pharma LLC), 201 Tresser Boulevard, Stamford, CT 06901 (Virtual Manufacturer)
- Rhodes Pharmaceuticals L.P. (to become Rhodes Pharmaceuticals LLC), 4701 International Blvd W, Wilson, NC 27893 (Virtual Manufacturer/Virtual Wholesaler)

Lists of Applicant Affiliates' products are found on the pages to follow.

Drug Establishments Current Registration Site

New Search (index.cfm)

Search Results for **Knoa**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Knoa Pharmaceuticals LLC	3002960808	132080875	MANUFACTURE;	4701 International Blvd W, Wilson, North Carolina (NC) 27893, United States (USA)	12/31/2026

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Thursday, May 28, 2026

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Attachment E

LLC Officer Information

Knoa Pharmaceuticals LLC
4701 International Boulevard W
Wilson, NC 27893

Each of the officers may be reached at the address above.

KNOA PHARMACEUTICALS LLC
4701 International Blvd W
Wilson, NC 27893

OFFICER INFORMATION

NAME	TITLE
Marc L. Kesselman	Chief Legal Officer & EVP Strategy and Corporate Affairs
Keith Darragh	Executive Vice President, Chief Financial Officer
Roxana Aleali	Vice President, General Counsel & Corporate Secretary
Donogh McGuire	Vice President, Chief of Technical Operations
Joseph Northington	Vice President, Quality

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "KNOA PHARMA LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTH DAY OF JANUARY, A.D. 2026.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "KNOA PHARMA LLC" WAS FORMED ON THE SECOND DAY OF SEPTEMBER, A.D. 2021.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 202715357

Date: 01-05-26

6211241 8300

SR# 20260017849

You may verify this certificate online at corp.delaware.gov/authver.shtml

North Carolina Department of Agriculture & Consumer Services

Food and Drug - Prescription Drug

Steve Troxler
Commissioner

Christina L. Waggett
Assistant Commissioner
for Consumer Protection

Anita MacMullan
Division Director

License Details for Knoa Pharmaceuticals LLC

Licensee Details	
Firm Name: Knoa Pharmaceuticals LLC	**License Type:** Manufacturer
Mailing Address:	**Physical Address:** 4701 International Boulevard W, Wilson, NC 27893
License Status: Active – In good standing	**License Number:** 37
Current Issue Date: 11/19/2025	**Discipline:** No
Original Issue Date: 12/15/2005	**License Expiration:** 12/31/2026
Search URL: https://apps.ncagr.gov/AgRSysPortalV2/licensesearch/fdpd/307774	

NCDA&CS
4400 Reedy Creek Road Raleigh, NC 27607-6465
1070 Mail Service Center, Raleigh, North Carolina 27699-1070
Main (984) 236-4820 : Fax: (919) 831-1323

Attachment H

Regarding the DEA Registration

Enclosed is a copy of Purdue Pharmaceuticals L.P.'s existing DEA Registration. A new DEA Registration reflecting the change of control and name change will be provided when it becomes available.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	03-31-2027	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-31-2026

PURDUE PHARMACEUTICALS LP
4701 INTERNATIONAL BLVD W
WILSON, NC 278939680

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	03-31-2027	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-31-2026

PURDUE PHARMACEUTICALS LP
4701 INTERNATIONAL BLVD W
WILSON, NC 278939680

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	03-31-2027	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-31-2026

PURDUE PHARMACEUTICALS LP
4701 INTERNATIONAL BLVD W
WILSON, NC 278939680

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

WESTCHESTER FIRE INSURANCE COMPANY

BOND RIDER

This Bond Rider ("Rider") is to be attached to and made part of part of the Pharmaceutical Wholesaler Surety Bond **(each which bear bond number K13519031)**.

WHEREAS, Westchester Fire Insurance Company, ("Surety") as surety, issued and/or executed that certain Pharmaceutical Wholesaler Surety Bond (together with any and all rider(s) and/or amendment(s) thereto, individually and collectively, the "Bond"), bearing bond number K13519031, on behalf of Purdue Pharmaceuticals L.P., Rhodes Pharmaceuticals L.P. and Purdue Pharma L.P., as principals, in favor of the Nevada State Board of Pharmacy, as obligee, having a penal sum of $100,000.00; and,

WHEREAS, in connection with that certain Eighteenth Amended Joint Chapter 11 Plan of Purdue Pharma L.P. and its Affiliated Debtors [Docket No. 8233] (together with all plan supplements as amended, modified, or supplemented from time to time, the "Plan") entered in the chapter 11 bankruptcy case titled *In re Purdue Pharma L.P. et al.*; which is pending in the United States Bankruptcy Court for the Southern District of New York (Case No. 19-23649 (jointly administered)), and that certain Findings of Fact, Conclusions of Law, and Order Confirming the Eighteenth Amended Joint Chapter 11 Plan of Purdue Pharma L.P. and its Affiliated Debtors ("Confirmation Order") [Docket No. 8263] confirming the Plan and whereby the Plan was substantially consummated and became effective on May 1, 2026 [Docket No.9133]; and,

WHEREAS, pursuant to the Plan, there has been a change to the corporate structure of Purdue Pharma L.P. and its Debtor Affiliates whereby Knoa Pharma LLC, Rhodes Pharmaceuticals LLC and Knoa Pharmaceuticals LLC ("Knoa") are deemed Principals on the Bond, and whereas Purdue Pharma L.P. transferred all of its assets and business to Knoa Pharma LLC and is no longer operating, and Rhodes Pharmaceuticals L.P. and Purdue Pharmaceuticals L.P. each converted their respective form from a limited partnership to a limited liability company and Purdue Pharmaceuticals changed its name, and by execution of this Rider, Knoa consents to the terms set forth herein; and,

In consideration of matters and terms described herein, the Surety and Knoa (jointly, the "Parties") each hereby consent to changing the name/identity of the Principal on the Bond, as follows:

> From: Purdue Parma L.P., Rhodes Pharmaceuticals L.P. and Purdue Pharmaceuticals L.P.
>
> To: Knoa Pharma LLC, Rhodes Pharmaceuticals LLC and Knoa Pharmaceuticals LLC

Except for the change of the name/identity of the Principals on the Bond ("Name Change"), neither this Rider nor the Plan or Confirmation Order varies, alters or extends any provision or condition of the Bond. Except for the Name Change, the Bond remains in full force and effect from the date

of its initial issuance in accordance with and subject to the terms and conditions of the Bond, which Bond is/are incorporated herein as if fully set forth herein, and nothing herein or in the Plan or Confirmation Order shall limit or expand, in any manner, the Surety's obligations under or in connection with the Bond.

By its execution of this Rider and otherwise, Knoa represents, warrants and agrees that it has provided any and all necessary consents to the execution of this Rider.

Signatures on this Rider that are transmitted by facsimile or email (as well as PDF copies of signatures) shall be accepted and deemed to be original signatures for all purposes and shall be binding on the parties. This Rider may be executed in counterparts; proof of this executed Rider shall require production of only one such counterpart duly executed by the party to be charged therewith.

This Rider constitutes the whole of the understanding, discussions, and agreements by and between the Parties. The terms and provisions of this Rider are contractual and not mere recitals, unless the Rider does not become effective pursuant to the terms hereof. The Parties acknowledge and agree that there have been no oral, written or other agreements of any kind as a condition precedent to, or to induce its execution and delivery of, this Rider. Any written or oral discussions conducted prior to the Effective Date of this Rider shall not in any way vary or alter the terms of this Rider.

The modification, amendment and/or waiver of this Rider, or of any of the provisions of this Rider, shall not become effective unless executed in writing by the party to be charged with such modification, amendment and/or waiver, in each case by a duly authorized representative.

This Rider is effective May 1, 2026.

Signed, sealed and dated this 12th day of May, 2026

Westchester Fire Insurance Company

By: _____
Print Name: Annette Audinot
Print Title: Attorney-In-Fact

Knoa Pharma LLC

By: _____
Print Name: Keith Darragh
Print Title: EVP, CFO

Rhodes Pharmaceuticals LLC

By: _____
Print Name: Keith Darragh
Print Title: EVP, CFO

Knoa Pharmaceuticals LLC

By: _____
Print Name: Keith Darragh
Print Title: EVP, CFO

[INSERT OTHER REQUIRED DOCUMENTS, *I.E.*,
NOTARIES; POWER OF ATTORNEY; ETC.]

State of New York
County of Kings } ss:

On May 12, 2026, before me, a Notary Public in and for said County and State, residing therein, duly commissioned and sworn, personally appeared

Annette Audinot

known to me to be Attorney-in-Fact of Westchester Fire Insurance Company the corporation described in and that executed the within and foregoing instrument, and known to me to be the person who executed the said instrument in behalf of the said corporation, and he duly acknowledged to me that such corporation executed the same.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal, the day and year stated in this certificate above.

My Commission Expires November 19, 2028

Terry Ann Gonzales-Selman Notary Public

TERRY ANN GONZALES-SELMAN
Notary Public, State of New York
No. 01GO6272513
Qualified in Kings County
Commission Expires November 19, 2028

Individual Acknowledgment

State of _____
County of _____

On the _____ day of _____, 20_____, before me personally appeared _____ to me known and known to me to be the person described in and who executed the foregoing instrument and ____he____ thereupon acknowledged to me that ____he___ executed the same.

_____
Notary Public

Partnership/L.L.C. Acknowledgment

State of Connecticut
County of Fairfield

On the 15th day of May, 2026, before me personally appeared Keith Darragh to me known and known to me to be one of the firm of Knoa Pharma LLC, Knoa Pharmaceuticals LLC, and Rhodes Pharmaceuticals LLC described in and who executed the foregoing instrument and _____he_____ thereupon acknowledged to me that ___he___ executed the same as and for the act and deed of said firm.

Emily P. Casinelli
Notary Public, State of Connecticut
My Commission Expires Jan. 31, 2027

Emily P. Casinelli
Notary Public

Corporate Acknowledgment

State of _____
County of _____

On the _____day of _____, 20_____, before me personally appeared _____ to me known, who being by me duly sworn, did depose and say the _____he____ is the _____ _____ of the _____ the corporation described in and which executed the foregoing instrument that _____he_____ knows the seal of said corporation, that the seal affixed to said instrument is such corporate seal, that it was so affixed by order of the board of directors of said corporation, and that _____he_____ signed his name thereto by like order.

_____
Notary Public

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Delaware corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint

Annette Audinot

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **19th** day of **July, 2024**.

Rupert HD Swindells Assistant Secretary

Warren Eichhorn, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss.

On this **19th** day of **July, 2024** before me, a Notary Public of New Jersey, personally came Rupert HD Swindells and Warren Eichhorn, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Rupert HD Swindells and Warren Eichhorn, being by me duly sworn, severally and each for himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

Albert Contursi
NOTARY PUBLIC OF NEW JERSEY
No 50202369
Commission Expires August 22,2027

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Rupert HD Swindells, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this May 12, 2026

Rupert HD Swindells, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903-3493 Fax (908) 903-3656 e-mail: surety@chubb.com

WESTCHESTER FIRE INSURANCE COMPANY

STATEMENT OF ASSETS, LIABILITIES AND SURPLUS TO POLICYHOLDERS

Statutory Basis

December 31, 2025

(in thousands)

ASSETS		*LIABILITIES AND SURPLUS TO POLICYHOLDERS*	
Cash, Cash Equivalents, and ST Investments	$ 6,557	Outstanding Losses and Loss Expenses	$ -
U.S. Government Bonds	17,259	Reinsurance Payable on Losses and Expenses	-
Non-US Government Bonds	289	Unearned Premiums	-
Issuer Credit Obligations ("ICO") Bonds	7,594	Ceded Reinsurance Premiums Payable	-
Asset-Backed Securities ("ABS") Bonds	42,474	Other Liabilities	190,579
Stocks	-		
Other Invested Assets	4,428		
TOTAL INVESTMENTS	78,581	TOTAL LIABILITIES	190,579
Investments in Affiliates		Capital Stock	5,000
Premiums Receivable	-	Paid-In Surplus	40,960
Other Assets	173,325	Unassigned Funds	15,367
		SURPLUS TO POLICYHOLDERS	61,327
TOTAL ADMITTED ASSETS	$ 251,906	TOTAL LIABILITIES AND SURPLUS	$ 251,906

Investments are valued in accordance with requirements of the National Association of Insurance Commissioners. At December 31, 2025, investments with a carrying value of $11,903,096 were deposited with government authorities as required by law.

STATE OF PENNSYLVANIA

COUNTY OF PHILADELPHIA

John Taylor, being duly sworn, says that he is Senior Vice President of Westchester Fire Insurance Company and that to the best of his knowledge and belief the foregoing is a true and correct statement of the said Company's financial condition as of the 31 st day of December, 2025.

Sworn before me this March 11, 2026

Senior Vice President

Jaime L. Yates

Notary Public

September 19, 2027

My commission expires

Commonwealth of Pennsylvania - Notary Seal
Jaime L. Yates, Notary Public
Philadelphia County
My commission expires September 19, 2027
Commission number 1357070

Member, Pennsylvania Association of Notaries

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. K13519031

Application/License No. _____

Purdue Pharmaceuticals L.P. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 4701 Wilson Drive, Wilson, NC 27893 (Address of Applicant/Principal), as PRINCIPAL, and Westchester Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Pennsylvania (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 436 Walnut Street, Philadelphia, PA 19106-3703 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 08, 2018 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 8th day of March, 2018.

APPLICANT/PRINCIPAL

Purdue Pharmaceuticals L.P.

Authorized Representative

SURETY COMPANY

Westchester Fire Insurance Company

Surety Company's Representative

Jessica Iannotta, Attorney-in-fact

print name

NV Non Resident Producer, License No. 3155198

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Kelly O'Malley

Witness Annette Leuschner

Countersigned by:

N/A

Nevada Resident Agent

Power of Attorney

WESTCHESTER FIRE INSURANCE COMPANY

Know all men by these presents: That WESTCHESTER FIRE INSURANCE COMPANY, a corporation of the Commonwealth of Pennsylvania pursuant to the following Resolution, adopted by the Board of Directors of the said Company on December 11, 2006, to wit:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such persons written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested.

Does hereby nominate, constitute and appoint Annette Leuschner, April D Perez, James P Holland, Jessica Iannotta, Kelly O'Malley, Kristin S Bender, Marisol Mojica, Theresa Giraldo all of the City of MORRISTOWN, New Jersey, each individually if there be more than one named, its true and lawful attorney-in-fact, to make, execute, seal and deliver on its behalf, and as its act and deed any and all bonds, undertakings, recognizances, contracts and other writings in the nature thereof in penalties not exceeding SEVENTY MILLION DOLLARS & ZERO CENTS ($70,000,000 00) and the execution of such writings in pursuance of these presents shall be as binding upon said Company, as fully and amply as if they had been duly executed and acknowledged by the regularly elected officers of the Company at its principal office,

IN WITNESS WHEREOF, the said Stephen M. Haney, Vice-President, has hereunto subscribed his name and affixed the Corporate seal of the said WESTCHESTER FIRE INSURANCE COMPANY this 3 day of October 2017

WESTCHESTER FIRE INSURANCE COMPANY

Stephen M. Haney , Vice President

COMMONWEALTH OF PENNSYLVANIA
COUNTY OF PHILADELPHIA ss.

On this 3 day of October, 2017 before me, a Notary Public of the Commonwealth of Pennsylvania in and for the County of Philadelphia came Stephen M. Haney ,Vice-President of the WESTCHESTER FIRE INSURANCE COMPANY to me personally known to be the individual and officer who executed the preceding instrument, and he acknowledged that he executed the same, and that the seal affixed to the preceding instrument is the corporate seal of said Company; that the said corporate seal and his signature were duly affixed by the authority and direction of the said corporation, and that Resolution, adopted by the Board of Directors of said Company, referred to in the preceding instrument, is now in force.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my official seal at the Cityof Philadelphia the day and year first above written.

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
KAREN E. BRANDT, Notary Public
City of Philadelphia, Phila. County
My Commission Expires Sept. 28, 2018

Notary Public

I, the undersigned Assistant Secretary of the WESTCHESTER FIRE INSURANCE COMPANY, do hereby certify that the original POWER OF ATTORNEY, of which the foregoing is a substantially true and correct copy, is in full force and effect.

In witness whereof, I have hereunto subscribed my name as Assistant Secretary, and affixed the corporate seal of the Corporation, this 8th day of March 2018

Dawn M. Chloros, Assistant Secretary

THIS POWER OF ATTORNEY MAY NOT BE USED TO EXECUTE ANY BOND WITH AN INCEPTION DATE AFTER OCTOBER 03, 2019.

DocuGard #04546 contains a security pantograph, blue background, heat-sensitive ink, coin-reactive watermark, and microtext printing on border.

WESTCHESTER FIRE INSURANCE COMPANY

FINANCIAL STATEMENT **DECEMBER 31, 2016**

ADMITTED ASSETS

BONDS	$1,492,813,519
SHORT - TERM INVESTMENTS	34,890,369
STOCKS	450,903
REAL ESTATE	0
CASH ON HAND AND IN BANK	19,880,440
PREMIUM IN COURSE OF COLLECTION*	69,254,246
INTEREST ACCRUED	14,505,011
OTHER ASSETS	132,649,982
TOTAL ASSETS	$1,764,444,470

LIABILITIES

RESERVE FOR UNEARNED PREMIUMS	$200,260,562
RESERVE FOR LOSSES	851,003,190
RESERVE FOR TAXES	16,081,016
FUNDS HELD UNDER REINSURANCE TREATIES	5,666,051
OTHER LIABILITIES	(11,412,992)
TOTAL LIABILITIES	1,061,597,827
CAPITAL: 70,000 SHARES, $71.43 PAR VALUE	5,000,100
CAPITAL: PAID IN	304,543,059
AGGREGATE WRITE-INS FOR SPECIAL SURPLUS FUNDS	113,661,643
SURPLUS (UNASSIGNED)	279,641,841
SURPLUS TO POLICYHOLDERS	702,846,643
TOTAL	$1,764,444,470

(*EXCLUDES PREMIUM MORE THAN 90 DAYS DUE.)

STATE OF PENNSYLVANIA

COUNTY OF PHILADELPHIA

John Taylor, being duly sworn, says that he is Senior Vice President of Westchester Fire Insurance Company and that to the best of his knowledge and belief the foregoing is a true and correct statement of the said Company's financial condition as of the 31 st day of December, 2016.

Sworn before me this March 22, 2017

Senior Vice President

Notary Public

August 8, 2019
My commission expires

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
Diane Wright, Notary Public
City of Philadelphia, Philadelphia County
My Commission Expires Aug. 8, 2019
MEMBER, PENNSYLVANIA ASSOCIATION OF NOTARIES

SURETY RIDER

To be attached to and form a part of

Bond No. K13519031

dated effective March 8, 2018
(MONTH-DAY-YEAR)

executed by Purdue Pharmaceuticals L.P. , as Principal,
(PRINCIPAL)

and by Westchester Fire Insurance Company , as Surety,

in favor of Nevada State Board of Pharmacy
(OBLIGEE)

in consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to ~~changing~~

Adding the Principal name to the bond as follows:

Rhodes Pharmaceuticals L.P.
498 Washington Street
Coventry, RI 02816

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective February 26, 2020
(MONTH-DAY-YEAR)

Signed and Sealed August 27, 2020
(MONTH-DAY-YEAR)

Rhodes Pharmaceuticals L.P.
(PRINCIPAL)

By: _____
(PRINCIPAL)

Westchester Fire Insurance Company
(SURETY)

By: _____
April D. Perez, Attorney-In-Fact

WESTCHESTER FIRE INSURANCE COMPANY

S-0443/GEEF 10/99

CHUBB

Power of Attorney

Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint Annette Audinot, Kristin S. Bender, Jessica Iannotta, Kelly O'Malley and April D. Perez of Morristown, New Jersey; Megan Schlueter of Raleigh, North Carolina ----------

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY have each executed and attested these presents and affixed their corporate seals on this **2nd** day of **October, 2019**.

Dawn M. Chloros

Dawn M. Chloros, Assistant Secretary

Stephen M. Haney

Stephen M. Haney, Vice President

STATE OF NEW JERSEY

County of Hunterdon ss

On this **2nd** day of **October, 2019**, before me, a Notary Public of New Jersey, personally came Dawn M. Chloros, to me known to be Assistant Secretary of WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Dawn M. Chloros, being by me duly sworn, did depose and say that she is Assistant Secretary of WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and knows the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that she signed said Power of Attorney as Assistant Secretary of said Companies by like authority; and that she is acquainted with Stephen M. Haney, and knows him to be Vice President of said Companies; and that the signature of Stephen M. Haney, subscribed to said Power of Attorney is in the genuine handwriting of Stephen M. Haney, and was thereto subscribed by authority of said Companies and in deponent's presence.

Notarial Seal

KATHERINE J. ADELAAR
NOTARY PUBLIC OF NEW JERSEY
No. 2316685
Commission Expires July 18, 2024

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006 ; ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Dawn M. Chloros, Assistant Secretary of WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this August 27, 2020

Dawn M. Chloros

Dawn M. Chloros, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903-3493 Fax (908) 903-3656 e-mail: surety@chubb.com

DocuSign Envelope ID: CCF7D358-9B25-47C6-8B4C-6EAB7BF6431E

WESTCHESTER FIRE INSURANCE COMPANY

STATEMENT OF ASSETS, LIABILITIES AND SURPLUS TO POLICYHOLDERS

Statutory Basis

December 31, 2019

(In thousands)

ASSETS		*LIABILITIES AND SURPLUS TO POLICYHOLDERS*	
Cash and Short Term Investments	$ (17,346)	Outstanding Losses and Loss Expenses	$ -
United States Government, State and Municipal Bonds	106,879	Reinsurance Payable on Losses and Expenses	-
Other Bonds	56,172	Unearned Premiums	-
Stocks	28	Ceded Reinsurance Premiums Payable	-
Other Invested Assets	6,008	Other Liabilities	100,006
TOTAL INVESTMENTS	151,741	TOTAL LIABILITIES	100,006
Investments in Affiliates	-	Capital Stock	5,000
Premiums Receivable	-	Paid-In Surplus	59,856
Other Assets	92,830	Unassigned Funds	79,709
		SURPLUS TO POLICYHOLDERS	144,565
TOTAL ADMITTED ASSETS	$ 244,571	TOTAL LIABILITIES AND SURPLUS	$ 244,571

Investments are valued in accordance with requirements of the National Association of Insurance Commissioners, At December 31, 2019, investments with a carrying value of $12,787,328 were deposited with government authorities as required by law.

STATE OF PENNSYLVANIA

COUNTY OF PHILADELPHIA

John Taylor, being duly sworn, says that he is Senior Vice President of Westchester Fire Insurance Company and that to the best of his knowledge and belief the foregoing is a true and correct statement of the said Company's financial condition as of the 31 st day of December, 2019.

Subscribed before me this April 14 2020

John Taylor

Senior Vice President

Diane Wright

Notary Public

August 8, 2023

My commission expires

Commonwealth of Pennsylvania - Notary Seal
Diane Wright, Notary Public
Philadelphia County
My commission expires August 8, 2023
Commission number 1235745

Member, Pennsylvania Association of Notaries

SURETY RIDER

To be attached to and form a part of

Bond No. K13519031

dated effective March 8, 2018
(MONTH-DAY-YEAR)

executed by Purdue Pharmaceuticals L.P. and Rhodes Pharmaceuticals L.P. , as Principal,
(PRINCIPAL)

and by Westchester Fire Insurance Company , as Surety,

in favor of Nevada State Board of Pharmacy
(OBLIGEE)

in consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

The Principal name to:

Purdue Pharmaceuticals L.P, Rhodes Pharmaceuticals L.P. and Purdue Pharma L.P.

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective June 13, 2024
(MONTH-DAY-YEAR)

Signed and Sealed June 13, 2024
(MONTH-DAY-YEAR)

Purdue Pharmaceuticals L.P, Rhodes Pharmaceuticals L.P. and Purdue Pharma L.P.
(PRINCIPAL)

By: _____
(PRINCIPAL)

Westchester Fire Insurance Company
(SURETY)

By: _____
TerryAnn Gonzales-Selman, Attorney-In-Fact

S-0443/GEEF 10/99

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Wisconsin corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint Annette Audinot, Terry Ann Gonzales-Selman, Robert P. McDonough, Vincent Moy, Francesca Papa and Glenn Pelletiere of New York, New York

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **30th** day of **April 2024**.

Rupert HD Swindells, Assistant Secretary

Warren Eichhorn, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss.

On this **30th** day of **April, 2024** before me, a Notary Public of New Jersey, personally came Rupert HD Swindells and Warren Eichhorn, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Rupert HD Swindells and Warren Eichhorn, being by me duly sworn, severally and each for himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

Albert Contursi
NOTARY PUBLIC OF NEW JERSEY
No 50202369
Commission Expires August 22,2027

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Rupert HD Swindells, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect,
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this June 13, 2024

Rupert HD Swindells, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903- 3493 Fax (908) 903- 3656 e-mail: surety@chubb.com

WESTCHESTER FIRE INSURANCE COMPANY

STATEMENT OF ASSETS, LIABILITIES AND SURPLUS TO POLICYHOLDERS

Statutory Basis

December 31, 2023

(in thousands)

ASSETS		*LIABILITIES AND SURPLUS TO POLICYHOLDERS*	
Cash, Cash Equivalents, and ST Investments	$ 6,916	Outstanding Losses and Loss Expenses	$ -
United States Government, State and		Reinsurance Payable on Losses and Expenses	-
Municipal Bonds	55,420	Unearned Premiums	-
Other Bonds	7,550	Ceded Reinsurance Premiums Payable	-
Stocks	-	Other Liabilities	204,011
Other Invested Assets	4,092		
TOTAL INVESTMENTS	73,978	TOTAL LIABILITIES	204,011
Investments in Affiliates	-	Capital Stock	5,000
Premiums Receivable	-	Paid-In Surplus	40,980
Other Assets	184,387	Unassigned Funds	8,394
		SURPLUS TO POLICYHOLDERS	54,354
TOTAL ADMITTED ASSETS	$ 258,365	TOTAL LIABILITIES AND SURPLUS TO POLICYHOLDERS	$ 258,365

Investments are valued in accordance with requirements of the National Association of Insurance Commissioners. At December 31, 2023, investments with a carrying value of $11,611,787 were deposited with government authorities as required by law.

STATE OF PENNSYLVANIA

COUNTY OF PHILADELPHIA

John Taylor, being duly sworn, says that he is Senior Vice President of Westchester Fire Insurance Company and that to the best of his knowledge and belief the foregoing is a true and correct statement of the said Company's financial condition as of the 31 st day of December, 2023.

Sworn before me this March 11, 2024

Senior Vice President

Diane Wright
Notary Public

August 8, 2027
My commission expires

Commonwealth of Pennsylvania - Notary Seal
Diane Wright, Notary Public
Philadelphia County
My commission expires August 8, 2027
Commission number 1235745
Member, Pennsylvania Association of Notaries

MARSH

INVOICE

Marsh USA LLC
New York NY
(212) 345-6000

Page	1 of 2
Invoice Total	**1,000.00 USD**
Invoice No.	335535630356
Invoice Date	05/20/2026
Client No.	3355300000

Billed To:
Antoinette Green
Purdue Pharma Manufacturing L.P.
One Stamford Forum
Stamford, CT 06901

Remittance Copy

Company earns and retains interest income on premium payments held by Marsh on behalf of insurers during the period between receipt of such payments from clients and the time such payments are remitted to the applicable insurer, where permitted by law.

Detach and remit this portion with your payment

Client No.	Invoice No.	Payment Due	Invoice Total	Amount Paid
3355300000	335535630356	Immediate	1,000.00 USD	

Thank you for your prompt payment.

Please indicate Invoice Number 335535630356 on your remittance.

Additionally, for ACH or wire payments, e-mail remittance detail to: FiduciaryserviceRequest.US@marsh.com

By ACH:
Bank Name: Bank of America
ACH Routing No: 071000039
Account Title: Marsh USA LLC
Account Number: 8188063077

By Wire:
Bank Name: Bank of America
Wire Routing Number: 026009593
Account Title: Marsh USA LLC
Account Number: 8188063077

By Mail:
Marsh USA LLC
P.O. Box 846015
Dallas, TX 75284-6015 USA

3355356303564 000010000033

MARSH

INVOICE

Marsh USA LLC
New York NY
(212) 345-6000

Page	2 of 2
Invoice Total	**1,000.00 USD**
Invoice No.	335535630356
Invoice Date	05/20/2026
Client No.	3355300000

Billed To:
Antoinette Green
Purdue Pharma Manufacturing L.P.
One Stamford Forum
Stamford, CT 06901

Surety Name	Bond No.	Effective Date	Expiration Date	Transaction Type	Description/ Type of Coverage	Item	Amount
Westchester Fire Insurance Co	K13519031	03/08/2026	03/08/2027	Original	Commercial Bond	PREMIUM	1,000.00

Invoice Comments:

Principal:Purdue Pharmaceuticals L.P, Rhodes Pharmaceuticals L.P. and Purdue Pharma L.P.
Obligee:Nevada State Board of Pharmacy
Bond Amount: $100,000.00
Bond Type - Description:License & Permit - Pharmaceutical Wholesaler
Requester:Antoinette (Toni) Green

Invoice Total (Payable in Full upon Receipt) 1,000.00

Company earns and retains interest income on premium payments held by Marsh on behalf of insurers during the period between receipt of such payments from clients and the time such payments are remitted to the applicable insurer, where permitted by law.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Knoa Pharmaceuticals LLC

Physical Address 4701 International Boulevard W

City Wilson State NC Zip 27893

Mailing Address (if different from physical address) same as above

City _____ State _____ Zip _____

Telephone 252-265-1900 Website _____

Licensing Company Email wilson.applications@pharma.com

Section 2: Personal Information

First Donogh Middle Martin Last McGuire

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 4701 International Boulevard W

City Wilson State NC Zip [redacted]

Telephone [redacted] Email Donogh.mcguire@pharma.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Applicant's initials _____

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Trinity College Dublin		1983-1987	
Address	City: Dublin	State: Ireland	Zip
Diploma/Degree obtained, if any: B.Sc. Pharmacy Degree			

School Name		From - To (MM/YY – MM/YY)	
St Muredach's College		1977-1983	
Address	City: Ballina	State: Ireland	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
Anticipated May 1, 2026	[redacted]	Wilson	NC	[redacted]
8/12 - Present		Wilson	NC	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials _____ 3

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)	
Knoa Pharmaceuticals LLC		Anticipated May 1, 2026	
Business Address	**City**	**State**	**Zip**
4701 International Blvd W	Wison	NC	27893
Phone	**Title**	**Number of Employed Hours**	
252-265-1900	Vice President, Chief of Technical Operations, VP, Technical Operations		
Description of Duties			
Responsible for all Manufacturing, Packaging and Distribution for US products in the brand and generic businesses, and generics division oversight.			

Business Name		From - To (MM/YY – MM/YY)	
Purde Pharmaceuticals L.P.		08/12-Present	
Business Address	**City**	**State**	**Zip**
4701 International Blvd We	Wilson	NC	27893
Phone	**Title**	**Number of Employed Hours**	
252-265-1900		6,000 +	
Description of Duties			
Responsible for all Manufacturing, Packaging and Distribution for US products in the brand and generic businesses, and generics division oversight.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Applicant's initials _____ 4

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	x	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/21/20	Pending	NJ		
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		U.S. District Court for the District of New Jersey		
Reason/Charge				
Plea Agreement				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
US Department of Justice / Purdue Pharma L.P.				
Name of Business/Industry/Entity				
Purdue Pharma L.P.				

Provide explanation below:

Purdue Pharmaceuticals L.P. is a direct subsidiary of Purdue Pharma L.P. ("PPLP"). On 10/21/20, PPLP entered into an agreement with the United States Department of Justice ("DOJ") to resolve DOJ's criminal and civil investigations of PPLP, including a criminal plea agreement (the "PPLP Plea Agreement"). Pursuant to the PPLP Plea Agreement, on 11/24/20, PPLP pled guilty to three felony counts to resolve all potential criminal charges against PPLP and its subsidiaries and affiliates with respect to the production, sale, marketing and distribution of opioid products between May 2007 and the present.

PPLP's sentencing hearing is currently scheduled for April 21, 2026 and a judgment of conviction will not be entered until after PPLP's sentencing hearing. Pursuant to the terms of PPLP Plea Agreement and the Plan of Reorganization confirmed in the pending Chapter 11 bankruptcy cases involving PPLP and its affiliates, Knoa Pharma LLC - a new entity formed to hold the assets of PPLP, including its ownership interests in subsidiaries - is expected to emerge from bankruptcy approximately seven days after the sentencing hearing. The PPLP Plea Agreement also permits PPLP to withdraw its guilty plea in certain circumstances prior to the sentencing hearing.

Original Signature (electronic, copies or stamps not accepted)

04/20/2026
Date

Applicant's initials

I, Donogh M. McGuire, **certify that as the designated representative for**

Knoa Pharmaceuticals LLC,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

Donogh M. McGuire
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/20/2026
Date

Applicant's initials

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Donogh M. McGuire
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/20/2026
Date

Please have this section completed in the presence of a Notary Public.

State of NORTH CAROLINA, ss. County of WILSON

I, DONOGH MCGUIRE, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

04/20/2026
Date

Subscribed and Sworn to before me this 20th day of April 2026.

Notary Public Signature

RIKKI L. BIZZELL
NOTARY PUBLIC
My Commission Expires
10/22/2028
WILSON COUNTY, NC

(Seal)

Applicant's initials

Employee Name	Position	Company
Moore, Joseph O	Sr. Engineer Proj Specialist II	UC7 Purdue Pharmaceuticals, LP
Griffin, William S	Manager Supp. Chain Planning & Procurement	UC7 Purdue Pharmaceuticals, LP
McCullough, Brian D	Diversion Control Specialist II	UC7 Purdue Pharmaceuticals, LP
Albert, Darrin D	Sr. Maintenance Mechanic	UC7 Purdue Pharmaceuticals, LP
Ward, Gregory A	Sr. Manager Diversion Control Group	UC7 Purdue Pharmaceuticals, LP
Wilson, Brett C	Diversion Control Specialist II	UC7 Purdue Pharmaceuticals, LP
Evans, Stella E	Director Corporate Security and Ethics & Compliance	UC7 Purdue Pharmaceuticals, LP
Kearney, Angela B	Director Talent Acquisition and Strategic HR Business Partner	UC7 Purdue Pharmaceuticals, LP
Coley, Christopher D	Pharmaceutical Process Specialist 1901219	UC7 Purdue Pharmaceuticals, LP
Radford, Dexter W	Sr. Quality Specialist I Lab Systems	UC7 Purdue Pharmaceuticals, LP
Thorne, Roger L	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Bass, Brian L	Pharmaceutical Process Specialist 1901219	UC7 Purdue Pharmaceuticals, LP
Armstrong, Stephanie D	Pharmaceutical Process Specialist 1902219	UC7 Purdue Pharmaceuticals, LP
Kriger, Etta R	Supervisor Quality Control	UC7 Purdue Pharmaceuticals, LP
Daniels, Fonya W	Sr. Technical Process Coordinator 1901219	UC7 Purdue Pharmaceuticals, LP
Hoskins, Kenneth S	Pharmaceutical Technology Scientist	UC7 Purdue Pharmaceuticals, LP
Artis, Barbara J	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Pittman, Bonnie B	Sr. Technical Process Coordinator 1901219	UC7 Purdue Pharmaceuticals, LP
Coleman, Derrick	Pharmaceutical Process Specialist 1901219	UC7 Purdue Pharmaceuticals, LP
Davis, Tina L	Quality Specialist II Prod Support	UC7 Purdue Pharmaceuticals, LP
Harris, Gwendolen L	Sr. Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Cannon, Susan M	Administrative Associate V 6200219	UC7 Purdue Pharmaceuticals, LP
Jordan, Edward R	Group Lead Distribution & Warehouse	UC7 Purdue Pharmaceuticals, LP
Lucas, Jamel C	Pharmaceutical Process Specialist 1901219	UC7 Purdue Pharmaceuticals, LP
Parker, Marty R	Sr. Manager Quality Control 6100219	UC7 Purdue Pharmaceuticals, LP
Page, Tony L	Supervisor Manufacturing	UC7 Purdue Pharmaceuticals, LP
Sawyer, Richard B	Manager Operations	UC7 Purdue Pharmaceuticals, LP
Lewis, Gregory D	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Strickland, David S	Packaging Lead Technician	UC7 Purdue Pharmaceuticals, LP
Croom, Steve J	Maintenance Mechanic	UC7 Purdue Pharmaceuticals, LP
Ward, David E	Executive Director Operations	UC7 Purdue Pharmaceuticals, LP
Johnson, Kelly D	Coord. II Reg. Compliance	UC7 Purdue Pharmaceuticals, LP
Williams, Cynthia E	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Cooke, Robert J	Diversion Control Specialist IV	UC7 Purdue Pharmaceuticals, LP
Varner-Munt, Sheri E	Sr. Validation Specialist II	UC7 Purdue Pharmaceuticals, LP
Yount, Lindsay A	Sr. Analyst Bi Supply Chain	UC7 Purdue Pharmaceuticals, LP
Williams, Don S	Distribution Technician II	UC7 Purdue Pharmaceuticals, LP
Taylor, Danny K	Tooling Specialist	UC7 Purdue Pharmaceuticals, LP
Evans, Jonathan D	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Meeks, Catherine E	Sr. Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Gray, William R	Sr. Maintenance Mechanic	UC7 Purdue Pharmaceuticals, LP
Ruffin, Ricky	Distribution Technician II	UC7 Purdue Pharmaceuticals, LP
Cowan, Robert A	Sr. Quality Specialist II Chemist	UC7 Purdue Pharmaceuticals, LP
Ethridge, Blair C	Technical Process Coordinator I	UC7 Purdue Pharmaceuticals, LP
Taybron, Timothy R	Pharmaceutical Process Specialist 1901219	UC7 Purdue Pharmaceuticals, LP
Kirby, James H	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Mastafiak, David	Sr. Quality Specialist I Chemist	UC7 Purdue Pharmaceuticals, LP
Bass, Jeffrey T	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Patel, Jayanesbhai	Supervisor Quality Control	UC7 Purdue Pharmaceuticals, LP
King Sr, Marco D	Pharmaceutical Process Specialist 1901219	UC7 Purdue Pharmaceuticals, LP
Buggs, Tray	Sr. Manager Finance 2100219	UC7 Purdue Pharmaceuticals, LP
Turner, Joseph Q	Maintenance Mechanic	UC7 Purdue Pharmaceuticals, LP
Richardson, Brandon A	Pharmaceutical Process Specialist 1902219	UC7 Purdue Pharmaceuticals, LP
Brantley, Karen L	Sr. Procurement Specialist	UC7 Purdue Pharmaceuticals, LP
Chi, Esther F	Manager Supply Chain Operations	UC7 Purdue Pharmaceuticals, LP

Kinal, Kenneth J	Director Engineering	UC7 Purdue Pharmaceuticals, LP
Herring, Edward M	Pharmaceutical Technology Scientist	UC7 Purdue Pharmaceuticals, LP
Holden, Elizabeth A	Pharmaceutical Process Specialist 1902219	UC7 Purdue Pharmaceuticals, LP
Moore, Ronnie	Distribution Technician II	UC7 Purdue Pharmaceuticals, LP
Carlisle, Jonathan	Director Finance 2100219	UC7 Purdue Pharmaceuticals, LP
Adams, Daniel A	Sr. Quality Specialist I 6100219	UC7 Purdue Pharmaceuticals, LP
Thornton, Colleen M	Director Quality Control	UC7 Purdue Pharmaceuticals, LP
Contri, Robert J	Packaging Maintenance Mechanic	UC7 Purdue Pharmaceuticals, LP
May, Dwyane A	Manager Quality	UC7 Purdue Pharmaceuticals, LP
Patel, Taylor R	Supervisor Quality Control	UC7 Purdue Pharmaceuticals, LP
Krebs, Heather S	Sr. Manager Quality Control 6100219	UC7 Purdue Pharmaceuticals, LP
Thompson, Anthony L	Distribution Technician II	UC7 Purdue Pharmaceuticals, LP
McKeeman, Gregory N	Sr. Manager EHS	UC7 Purdue Pharmaceuticals, LP
Ruotolo, Gabriel A	Manager Quality Control	UC7 Purdue Pharmaceuticals, LP
Olson, Roxane M	Sr. Specialist Tech. Ops.	UC7 Purdue Pharmaceuticals, LP
Sanders, Selina D	Coord. I Reg. Compliance	UC7 Purdue Pharmaceuticals, LP
Cieslinski, Brian D	Associate Director Operations	UC7 Purdue Pharmaceuticals, LP
Cheerla, Rakesh R	Sr. Quality Specialist I Method Development	UC7 Purdue Pharmaceuticals, LP
Gray, Colin M	Process Support Specialist	UC7 Purdue Pharmaceuticals, LP
Beach Jr, William C	Sr. Validation Specialist	UC7 Purdue Pharmaceuticals, LP
Palmer, Natalie N	Associate Director IT Business Partner	UC7 Purdue Pharmaceuticals, LP
Saunders III, Thomas F	Sr. Manager Tech Ops IT Support	UC7 Purdue Pharmaceuticals, LP
Price, Jason R	Supervisor Operations	UC7 Purdue Pharmaceuticals, LP
Rouse, Christopher M	Maintenance Technician 6600219	UC7 Purdue Pharmaceuticals, LP
Owens, Crystal E	Sr. Quality Specialist II Lab Systems	UC7 Purdue Pharmaceuticals, LP
Thompson, J'veston A	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Dupree, Tina M	Supervisor Manufacturing	UC7 Purdue Pharmaceuticals, LP
Skinnell, William R	Pharmaceutical Process Specialist 1901219	UC7 Purdue Pharmaceuticals, LP
Pender, Jacqueline L	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Gibson, Sean P	Sr. Engineering Project Specialist I	UC7 Purdue Pharmaceuticals, LP
Dalton, Joey W	Supervisor Manufacturing	UC7 Purdue Pharmaceuticals, LP
Perry, Joshua A	Quality Specialist II Lab Systems 6100219	UC7 Purdue Pharmaceuticals, LP
Barnes, Howard W	Pharmaceutical Process Specialist 1901219	UC7 Purdue Pharmaceuticals, LP
Lee, Jason G	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Kroese, Michael R	Executive Director Supply Chain	UC7 Purdue Pharmaceuticals, LP
Denny, Scott P	Associate Director Quality 6200219	UC7 Purdue Pharmaceuticals, LP
Roberts, Terumi J	Quality Specialist III Chemist	UC7 Purdue Pharmaceuticals, LP
Sexton, Adam L	Instrumentation Controls and Automation Lead Technician	UC7 Purdue Pharmaceuticals, LP
Winstead Jr, Bobby G	Distribution Technician III	UC7 Purdue Pharmaceuticals, LP
Phillips, Stephanie C	Sr. Quality Specialist I Method Development	UC7 Purdue Pharmaceuticals, LP
Reed, Chad H	Sr. Pharmaceutical Technology Scientist	UC7 Purdue Pharmaceuticals, LP
Taylor, Angela P	Sr. Pharmaceutical Technology Scientist	UC7 Purdue Pharmaceuticals, LP
Johnson, Dalton	Quality Specialist III Metrology	UC7 Purdue Pharmaceuticals, LP
Rider, Kelsey M	Sr. Quality Specialist I Method Development	UC7 Purdue Pharmaceuticals, LP
Heijboer, Abraham	Associate Director Tech Ops IT Systems	UC7 Purdue Pharmaceuticals, LP
Holding, Allison B	Quality Specialist III Chemist	UC7 Purdue Pharmaceuticals, LP
Eagle, Timothy M	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Addicks, William J	Director Pharmacy Technology	UC7 Purdue Pharmaceuticals, LP
Edwards, Marques	Pharmaceutical Process Specialist 1901219	UC7 Purdue Pharmaceuticals, LP
Bonta, Dustin C	Distribution Technician II	UC7 Purdue Pharmaceuticals, LP
Vaughan, Robert J	Distribution and Inventory Technician II	UC7 Purdue Pharmaceuticals, LP
Arrington, Desman L	Sr. Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Curtis, Stafford J	Sr. Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Herwick, Jonathan K	Pharmaceutical Technician (Granulation/Blending)	UC7 Purdue Pharmaceuticals, LP
Perry, Patrice	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Atkinson, Robert N	Operations Support Technician	UC7 Purdue Pharmaceuticals, LP

Wiggins III, Lawrence	Pharmaceutical Process Specialist 1901219	UC7 Purdue Pharmaceuticals, LP
Bryant, Renard C	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Faison, Monty M	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Gregory, Cole	Packaging Lead Technician	UC7 Purdue Pharmaceuticals, LP
Jones, Emily	Quality Specialist III Chemist	UC7 Purdue Pharmaceuticals, LP
Ramirez Jr, Jose	Pharmaceutical Technology Scientist	UC7 Purdue Pharmaceuticals, LP
Clark, James	EHS Specialst	UC7 Purdue Pharmaceuticals, LP
Hinnant, Bernice	Distribution Technician I	UC7 Purdue Pharmaceuticals, LP
Scott, John R	Pharmaceutical Process Specialist 1901219	UC7 Purdue Pharmaceuticals, LP
Connell, Erin	Quality Specialist II Chemist 6100219	UC7 Purdue Pharmaceuticals, LP
Jones, Christopher A	Sr. QA Specialist I	UC7 Purdue Pharmaceuticals, LP
Robinson, Johnny	MRO Storeroom Specialist	UC7 Purdue Pharmaceuticals, LP
Anderson, Monica P	Sr. CMC Data and Process Scientist	UC7 Purdue Pharmaceuticals, LP
Fortuna, Joan	QC Laboratory Technician II	UC7 Purdue Pharmaceuticals, LP
Godwin, Connor V	Quality Specialist III Chemist	UC7 Purdue Pharmaceuticals, LP
Howell, Damon	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Edwards, Taylor	Coord. II Reg. Compliance	UC7 Purdue Pharmaceuticals, LP
Battle, Damarious D	Packaging Maintenance Mechanic	UC7 Purdue Pharmaceuticals, LP
Dickerson, Reginald D	Pharmaceutical Technician (Granulation/Blending)	UC7 Purdue Pharmaceuticals, LP
Rushford, Cameron	Quality Specialist II Chemist 6100219	UC7 Purdue Pharmaceuticals, LP
Artis, Bobby R	Sr. Analyst Tech Ops IT Support	UC7 Purdue Pharmaceuticals, LP
Vaughan-Darden, Patricia L	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Locke, Cody	Quality Specialist III Chemist	UC7 Purdue Pharmaceuticals, LP
Whitfield, Gwendolyn A	Sr. Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Smith, Levy B	Sr. Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Shearin, Kenneth A	Packaging Maintenance Mechanic	UC7 Purdue Pharmaceuticals, LP
Thompson, Jameka	Packaging Lead Technician	UC7 Purdue Pharmaceuticals, LP
Faison, Montoria	Sr. Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Collins, Tshauna	Distribution and Inventory Technician II	UC7 Purdue Pharmaceuticals, LP
Chen, Xin W	Quality Specialist II Chemist 6100219	UC7 Purdue Pharmaceuticals, LP
Mooring, William	Sr. Manager Maintenance	UC7 Purdue Pharmaceuticals, LP
Taylor, Joseph D	Sr. Technical Operations Specialist II	UC7 Purdue Pharmaceuticals, LP
McAteer, Donald C	Quality Specialist III Chemist	UC7 Purdue Pharmaceuticals, LP
Spencer Bonner, Sara E	Quality Specialist II Chemist 6100219	UC7 Purdue Pharmaceuticals, LP
Pittman, Kristen L	Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Bolla, Kalwinder S	Director Operations	UC7 Purdue Pharmaceuticals, LP
Dublin, Tyrell	Sr. Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Barnes, Jennifer L	Quality Specialist II Prod Support	UC7 Purdue Pharmaceuticals, LP
Gant, Kayla A	Quality Specialist III Chemist	UC7 Purdue Pharmaceuticals, LP
Smith, Matthew	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Boucher, Brittany	Quality Specialist III Chemist	UC7 Purdue Pharmaceuticals, LP
Brinson, Nathaniel	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Herman, April S	Manager Distribution/Warehouse	UC7 Purdue Pharmaceuticals, LP
Raney, Tony A	Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Crudup, Debbie	Sr. Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Collazo, Tania	Quality Specialist II Raw Materials	UC7 Purdue Pharmaceuticals, LP
Battle, Jomanda T	Quality Specialist II 6200219	UC7 Purdue Pharmaceuticals, LP
Wade, Billy H	Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Edmundson, Diamond	Sr. Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Smith, Candice M	Quality Specialist I Chemist	UC7 Purdue Pharmaceuticals, LP
Dupree, Dwight	Distribution Technician I	UC7 Purdue Pharmaceuticals, LP
Gooding, Brandon	Distribution Technician I	UC7 Purdue Pharmaceuticals, LP
Trimble, Malcolm	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Ebron, Tinneia	Distribution Technician I	UC7 Purdue Pharmaceuticals, LP
Edwards, Ryan L	Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Evans, Candace B	Quality Specialist I Chemist	UC7 Purdue Pharmaceuticals, LP

Robinson, Astazzia D	Quality Specialist I Chemist	UC7 Purdue Pharmaceuticals, LP
Fronczke, Kirk	Maintenance Technician 6600219	UC7 Purdue Pharmaceuticals, LP
Jones, Christopher W	Project Engineer Manager	UC7 Purdue Pharmaceuticals, LP
Barnes, Aneesha J	Sr. Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Davis, Towanda	Sr. Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Islam, Rafiqul	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Battle, Anthony T	Quality Specialist II Prod Support	UC7 Purdue Pharmaceuticals, LP
Chandler, Zachary W	Sr. Manager Project Engineering Mgmt	UC7 Purdue Pharmaceuticals, LP
White, Ashlee-Danielle R	Sr. Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Cupples, Shawn D	Sr. Quality Specialist II Metrology	UC7 Purdue Pharmaceuticals, LP
Barnes, Linda H	Sr. Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Winborne, James D	Instrumentation Technician	UC7 Purdue Pharmaceuticals, LP
Tyndall, Carlos R	Manager Packaging Operations	UC7 Purdue Pharmaceuticals, LP
Williams, Alneeiqua	Sr. Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Anugu, Ramshankerrao R	Supervisor Quality Control	UC7 Purdue Pharmaceuticals, LP
Jones, Maurice	Distribution Technician I	UC7 Purdue Pharmaceuticals, LP
Smith, Karen D	Distribution Technician I	UC7 Purdue Pharmaceuticals, LP
Senter, Kathleen M	Associate Director Supply Chain Operations	UC7 Purdue Pharmaceuticals, LP
Hebbard, James E	Sr. Specialist Tech. Ops.	UC7 Purdue Pharmaceuticals, LP
Johnson, Charles B	Maintenance Mechanic	UC7 Purdue Pharmaceuticals, LP
Bissette, Harley D	Supervisor Technical Training	UC7 Purdue Pharmaceuticals, LP
Styron, Daniel B	Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Avery, Johnny J	Instrumentation Technician	UC7 Purdue Pharmaceuticals, LP
Harris, Shanta	Quality Specialist II Chemist 6100219	UC7 Purdue Pharmaceuticals, LP
Smith, Benjamin C	Maintenance Planner/Scheduler	UC7 Purdue Pharmaceuticals, LP
Thompson, Billie R	Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Bynum, Camari T	Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Robinson, Rashad E	Quality Specialist II Chemist 6100219	UC7 Purdue Pharmaceuticals, LP
Brown, Roger A	Quality Specialist III Chemist	UC7 Purdue Pharmaceuticals, LP
Munoz, Diego R	Associate Director Operations	UC7 Purdue Pharmaceuticals, LP
Cox, Trevor	Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Allen, Alexandra D	Operations Support Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Humphrey, Tyler E	Maintenance Mechanic	UC7 Purdue Pharmaceuticals, LP
Loomis, Thomas	Packaging Maintenance Mechanic	UC7 Purdue Pharmaceuticals, LP
Coleman, Steven T	Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Lucas, Celeste' Tina	Sr. Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Blue, Daisha	Intern 6900219	UC7 Purdue Pharmaceuticals, LP
Hall, Joseph H	Sr. Pharmaceutical Technician 1901219	UC7 Purdue Pharmaceuticals, LP
Dunston, Lytoya	Intern 6100219	UC7 Purdue Pharmaceuticals, LP
Moore, Damien E	Pharmaceutical Technician 1902219	UC7 Purdue Pharmaceuticals, LP
Williams, Christy M	Sr. QA Specialist I Documentation Systems	UC7 Purdue Pharmaceuticals, LP
Ragin, James D	Associate Director Operational Excellence	UC7 Purdue Pharmaceuticals, LP

14

14A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmaceutical Technician IN TRAINING (PTT) Application

Non-Refundable $50 fee

Rev (03/16/2023)

Y

Section 1: General Information

First: Ingrid Middle: F Last: Nunez Blanquisel

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: N.V Zip: 89129

Telephone: [redacted] Email: [redacted]

Section 2: Program of Training for Pharmaceutical Technicians (Complete this section ONLY if you are enrolled in a PT school or training program.) NAC 639.258

Program/School Name: Northwest Career College

Address: 7398 Smoke Ranch Road

City: Las Vegas State: NV Zip: 89128

Name of Program Director: Samantha Huntsman

Signature of Program Director: [signature]

Section 3: Employment Information

Pharmacy Name: License #:

Address:

City: State: Zip:

Section 4: Age and Education Requirements (You do not qualify to be a PT if you answer "NO" in this section.)	**Yes**	**No**
1. Are you 18 years of age or older?	✓	
2. Are you a high school graduate or the equivalent?	✓	

High School Name: Legacy high school Graduation Date OR Date GED obtained (mm/yy): 6/2017

Address: 150 Deer Springs Way

City: N. Las Vegas State: N.V Zip: 89084

Section 5: Military Service (NRS 622.120)	**Yes**	**No**
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 6: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 7: Personal and Professional History		
Before answering the questions below, please INITIAL to the right to attest you have read and understand the following: WARNING You MUST provide truthful and complete responses to the questions on this application. If you omit information or provide false or misleading responses, including any failure to disclose past arrests or expunged convictions, this may be a basis for denial of your application and may result in disciplinary action against any other license or registration you hold from the Board.	Initials PN	
	Yes	**No**
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state even if the case or charge has been dismissed, sealed, acquitted, or expunged?	✓	
3. Have you been the subject of a board citation or administrative action whether completed or pending in any state?		✓
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 7 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
		LA	New Orleans	
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
trassposing				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

I was trassposing a ~~petoli~~ Private property the year 2022

Original Signature (electronic, copies or stamps not accepted)

6/3/26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I understand that Nevada law requires a registered pharmaceutical technician in training who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Paola Nunez

Print Name

Original Signature (electronic, copies or stamps not accepted)

6/3/26

Date

Board Use Only	Date Received: 6/15/26	Amount: $50 CH 1095743263

Nevada State Board of Pharmacy

Case No: 22-5027 *City, State:* Jefferson, Louisiana *Arrest Date:* 11/09/2022

To whom it may concern,

I am submitting this statement to provide context regarding a misdemeanor conviction from 2022 and to express my sincere remorse for the decisions that led to that incident. In 2022, I was convicted of misdemeanor trespassing and possession of a Schedule II controlled substance. The incident occurred while I was with individuals who were a negative influence in my life. I was present in a residence where I did not have permission to be, and I was found in possession of a Schedule II controlled substance. Although there were circumstances surrounding the incident that involved poor judgment and being associated with the wrong people, I understand that I am ultimately responsible for the choices I made that day. I take full accountability for my actions and deeply regret the decisions that led to my arrest and conviction.

That experience became a turning point in my life. I recognized that I needed to make significant changes, and I made the decision to seek help by completing a rehabilitation program. During that process, I learned the importance of accountability, healthy decision-making, and taking responsibility for my actions. My recovery gave me a new perspective on life and strengthened my commitment to living with integrity and purpose.

After successfully completing rehabilitation, I chose to continue giving back by volunteering at the rehabilitation center that helped me through my recovery. Supporting others as they worked toward rebuilding their lives was an incredibly meaningful experience. It reinforced my desire to help people, serve my community, and live a life that reflects compassion, responsibility, and honesty.

Since my conviction in 2022, I have remained out of legal trouble and have dedicated myself to becoming a responsible, dependable, and trustworthy individual. I understand that trust must be earned through consistent actions, and I have worked hard to demonstrate my commitment to personal growth and positive change every day.

I am passionate about becoming a Pharmacy Technician because I want to build a career centered on helping others. Pharmacy professionals play an essential role in ensuring patients receive safe and accurate medications, and I understand the responsibility that comes with that position. My past experiences have taught me the importance of accountability, ethical decision-making, and following all laws, policies, and professional standards. These lessons have shaped the person I am today and have motivated me to pursue a career where I can make a positive impact on the lives of others.I respectfully ask that my application be considered in light of the substantial growth and rehabilitation I have demonstrated since 2022. While I cannot change my past, I have learned from it, accepted responsibility for it, and committed myself to living a life defined by integrity, service, and accountability. I am dedicated to earning the trust of the Board, my future employer, my coworkers, and the patients I hope to serve.

Thank you for your time and consideration.

Paolo Nunez Blanquisel

10016D

STATE OF LOUISIANA
DEPARTMENT OF PUBLIC SAFETY AND CORRECTIONS
DIVISION OF PROBATION AND PAROLE
BATON ROUGE, LOUISIANA

DATE: 06/21/24 LETTERFOP

s3Bs1S FIRST OFFENDER CERTIFICATION LETERs0Bs0S

PAOLO NUNEZ [redacted] Race/Sex: H/M
[redacted] DOB: [redacted]
SID# [redacted]

To Whom It May Concern:

The above defendant was sentenced by the Honorable RAYMOND STEIB, Judge of the 24TH JUDICIAL DISTRICT Court, Parish of JEFFERSON, State of Louisiana, under the above listed docket number(s) for the crime(s) of:

SCHEDULE II POSSESSION

According to the Department of Public Safety and Corrections, Division of Probation and Parole records, said defendant completed this sentence on DECEMBER 15, 2023 and is classified as a first felony offender and, meets the requirements to receive a first offender pardon as provided by Article 1, Section 20, and Article 4, Section 5(E) (1), of the Louisiana Constitution.

The automatic first offender pardon does not restore you to a state of innocence. A full pardon granted by the Governor of the State of Louisiana will restore you to a state of innocence. The automatic first offender pardon is still subject to laws prohibiting the right to receive, possess or transport a firearm. Additionally, you may be subject to the Federal firearms prohibitions. Any questions regarding these legal provisions should be directed to your attorney or the FBI-NICS section.

The first offender pardon is also subject to Louisiana Constitution Article 1, Section 10 (C) and does not restore the right to qualify as a candidate for elective public office or take public office or appointment of honor, trust, or profit for a period of more than fifteen (15) years after completion of the original sentence.

This pardon does not constitute a waiver of any unpaid court costs, restitution, or past probation and parole fees. Under Act 399 of the 2013 Louisiana Regular Legislative Session, any debt owed by you to the Department of Public Safety and Corrections and/or the Louisiana Parole Board will be filed as a claim with the Department of Revenue, Office of Debt Recovery (ODR) for further collection activity. ODR may charge an additional collection fee up to 25% to be added to your current debt. ODR may also file a claim with the United States Treasury Program. All payments "eligible for offset" will be seized, up to the amount of your liability plus any additional fees.

Corey Acosta
Probation and Parole Director

Tobie Lamy
District Administrator

cc: Defendant
Clerk of Court
EJD
State Police (early termination only)

15

15A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

CONTROLLED SUBSTANCE APPLICATION

Non-Refundable $200 fee

Rev (01/05/2023)

(This application cannot be used by PA's or APRN's)

Select the Controlled Substance Schedules you are applying to prescribe (optometrists are limited to schedules III, IV, and V.)

☐ Schedule I ☒ Schedule II ☒ Schedule III ☒ Schedule IV ☒ Schedule V

Section 1: Personal Information

First: Jaywant Middle: Philip Last: Parmar

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Home Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Degree: MD Practitioner License #: NV 25614 Specialty: Radiology

(You MUST have a current and active practice license with your respective BOARD to apply for and maintain a controlled substance registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name (if any): Reno Radiological Associates

Practice Address: 1155 Mill St Suite #:

City: Reno State: NV Zip: 89502

Telephone: 317.614.9608 Fax: 317.324.9105 Email: rivy@zotecpartners.com

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	✔	
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5:1. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
July 2025	Compliant	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		Voluntary treatment Nevada Professionals Health Program		
Reason/Charge				
Voluntary treatment related to alcohol use; no charge				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
n/a		n/a		
Name of Business/Industry/Entity				
Nevada Professionals Health Program				

Provide explanation below:

I am answering "Yes" out of an abundance of caution based on the wording of this question. In 2025, following my arrest for impaired driving involving THC (not alcohol, please see explanation 5:2), I engaged in significant self-reflection and voluntarily sought treatment related to my alcohol use. Although alcohol was not involved in the arrest, the event prompted me to evaluate my overall health and well-being and to pursue treatment proactively. At no time did I practice medicine while under the influence of alcohol or THC. I do not believe that my use of alcohol or THC impaired my ability to perform the essential functions of my medical license, and there were no clinical events, patient safety concerns, or allegations of impairment related to my medical practice. I completed the recommended treatment, currently participate in the Nevada Professionals Health Program, remain fully compliant with all monitoring requirements, and have no current substance use or impairment affecting my ability to practice medicine safely.

I authorize the Nevada State Board of Pharmacy to contact Mark Chase, Ph.D., Executive Director of the Nevada Professionals Health Program, regarding my participation in and compliance with the Nevada Professionals Health Program. Dr. Chase may verify my compliance with the program and provide information regarding my current monitoring status and ability to practice medicine safely.

Mark Chase, Ph.D.
Executive Director, Nevada Professionals Health Program
7473 West Lake Mead Blvd., Suite 213
Las Vegas, NV 89128
Phone: (702) 562-1230
Cell: [redacted]
Email: Mark@nvphp.com

Original Signature (electronic, copies or stamps not accepted)

7/22/2026
Date

Section 5: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	✔	
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✔	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 5 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5:2. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
7/22/2025	1/7/2026	Utah	St. George	Washington

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
255710489	Washington County Justice Court, Utah

Reason/Charge
Misdemeanor impaired driving

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
State of Utah / Jaywant P. Parmar, III, M.D.	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below:

In July 2025, I briefly fell asleep while stopped at a traffic signal, which resulted in a traffic stop. There was no motor vehicle collision, no injuries, and no alcohol involvement. Laboratory testing was positive only for THC. The matter was resolved on January 7, 2026, by a plea to misdemeanor impaired driving. I have fully complied with all court requirements, voluntarily obtained treatment, remain compliant with the Nevada Professionals Health Program (NVPHP), and do not currently use alcohol or THC. Please reference response to 5:1 for additional details regarding NVPHP.

Original Signature (electronic, copies or stamps not accepted)

7/22/2026
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jaywant Parmar MD	7/22/2026
Print Name (First, Last)	Date
Original Signature (electronic, copies or stamps not accepted)	7/22/2026
	Date

Board Use Only: Date Processed: 7/27/26	Amount: $700.00

Jaywant P. Parmar M.D.
Diplomate American Board of Radiology
[redacted]
Las Vegas, NV [redacted]
[redacted]

July 1, 2026

To Whom It May Concern,

I am submitting this statement to accompany the attached court disposition and lawyer communication regarding a Utah impaired driving matter.

This matter arose from a non-clinical driving incident on July 22, 2025. The impaired-driving matter was THC-related, not alcohol-related. There was no alcohol involved, no accident, no injury, and no patient-care or clinical involvement of any kind. I was not using or consuming marijuana at the time of the encounter.

The matter was resolved in Washington County Justice Court as a Class B misdemeanor impaired driving conviction. Associated additional charges were dismissed, as reflected in the attached court documentation.

I take this matter seriously and understand why it requires disclosure and review in the credentialing process. I am complying with the court's requirements. I have reported the matter to the state medical boards for the licenses I hold, as required. I have also voluntarily enrolled in the Nevada Physician Health Program and am fully compliant with its monitoring and follow-up requirements.

There has been no clinical impairment, no adverse patient-care event, and no limitation on my commitment to safe, professional medical practice. I remain committed to full transparency, compliance with all monitoring and reporting requirements, and maintaining the highest standards of judgment, professionalism, and patient safety.

Please let me know if any additional documentation or clarification would be helpful.

Sincerely,



Jaywant Parmar, MD

PALMER LITIGATION

January 12, 2026

RE: Case Resolution Addendum

To Whom it May Concern,

This addendum serves to confirm the resolution of the case referenced in my prior correspondence. On January 7, 2026, Mr. Jaywant Parmar was convicted of a single Class B misdemeanor charge of impaired driving in Washington County Justice Court.

Mr. Parmar is fully compliant with all court-mandated requirements, which do not include incarceration. It is pertinent to highlight that this matter did not involve patient care, clinical impairment, or any actions that would compromise professional standards or workplace conduct. Should you require further documentation or clarification regarding this matter, please feel free to contact me directly.

Very truly yours,

PALMER LITIGATION

William B. Palmer III, III, ESQ.

1361 E. Red Hills Pkwy., Suite B2
St. George, Utah 84770
Phone: 435-465-8733 Fax: 435-216-3644

The Order of the Court is stated below:
Dated: January 07, 2026 03:45:59 PM
/s/ DOUGLAS A WHITLOCK
Justice Court Judge

FIFTH JUDICIAL DISTRICT - WASHINGTON COUNTY JUSTICE COURT
WASHINGTON COUNTY, STATE OF UTAH

ST GEORGE CITY, Plaintiff, vs. JAYWANT PHILIP PARMAR, Defendant.	MINUTES SENTENCE, JUDGMENT, COMMITMENT Case No: 255710489 MD Judge: DOUGLAS WHITLOCK Date: January 7, 2026

PRESENT

Clerk: lisamm
Prosecutor: MILLER, MATTHEW
Defendant Present
The defendant is not in custody
Defendant's Attorney(s): PALMER, WILLIAM

DEFENDANT INFORMATION

Date of birth: [redacted]

CHARGES

1. IMPAIRED DRIVING - Class B Misdemeanor Plea: Guilty - Disposition: 01/07/26 {Guilty}

HEARING

TIME: 2:23 PM Agreement reached.

Attorney Palmer enters a guilty plea to count 1 DUI, to be sentenced as impaired for the defendant, counts 2, 3 and 4 are dismissed. Defendant understands by entering this plea it is a waiver of rights. BAC THC.

Court accepts the factual basis.

Defendant waives the 2-45 day right for sentencing, Defendant wants to be sentenced today.

SENTENCE JAIL

Based on the defendant's conviction of IMPAIRED DRIVING a Class B Misdemeanor, the defendant is sentenced to a term of 180 day(s) The total time suspended for this charge is 180 day(s).

SENTENCE FINE

Charge # 1 Fine: $1390.00

Suspended: $0.00

Surcharge: $690.00

Due: $1390.00

Total Fine: $1390.00

Total Suspended: $0

Total Surcharge: $690.00

Total Principal Due: $1390.00

Plus Interest

Defendant is to pay a fine of 1390.00 which includes the surcharge. Interest may increase the final amount due.

Fine payments are to be made to The Court. This can be paid online at: https://www.washco.utah.gov/departments/justice-court/.

The fine is to be paid in full by 02/28/2026.

OTHER NOTE

Pay fine together with post judgment interest. Court retains jurisdiction of the Defendant in order to collect the fine.

COMMUNITY SERVICE

Complete 48 hour(s) of community service.

Community service is to be completed by July 7, 2026.

SENTENCE COMMUNITY SERVICE NOTE

Community service may be done with any non-profit organization. Proof must be on letterhead signed by someone with authority from the organization, submitted to the court by July 7, 2026.

ORDER OF PROBATION

The defendant is placed on probation for 12 month(s).

Probation is to be supervised by Court Bench Probation.

* No law violations.

* Notify court of any mailing address, phone number or email change within 10 days.

* Complete DUI Screening/Assessment within 60 days, and if recommended, complete any treatment within 6 months, with proof to the court.

* If unable to comply with any part of this Order, the Defendant must contact the court or file a motion prior to the due date requesting a hearing and obtain an extension or modification at the hearing.

CERTIFICATE OF NOTIFICATION

I certify that a copy of the attached document was sent to the following people for case 255710489 by the method and on the date specified.

EMAIL: JAYWANT PHILIP PARMAR [redacted]

EMAIL: ROBERT COSSON ROBERT.COSSON@SGCITYUTAH.GOV

EMAIL: WILLIAM PALMER BILLY@PALMERLITIGATION.COM

01/07/26 /s/ LISA MITCHELL

Date: _____ _____

Signature

Failure to do so may result in sanctions, including, but not limited to: (1) revocation of probation; (2) execution of the imposed sentence; (3) issuance of an arrest warrant; (4) suspension of driving privileges

and (5) the accounts receivable shall be converted to a civil judgment and be sent to the Office of State Debt Collection for collection; OSDC could add up to 30% to the account receivable for its collection efforts;

The Civil judgment constitutes a lien; has the same effect and is subject to the same rules as a judgment for money in a civil action; and may be collected by any means authorized by law for the collection of a civil judgment.

* Defendant has the right to appeal to District Court within 28 days after the date of sentencing; request must be in writing. Defendant has the right to a new trial/hearing in District Court.

End Of Order - Signature at the Top of the First Page

Jaywant Philip Parmar

License Number:
25614

License Type:
Medical Doctor

License Status:
Active

Initial License Date:
Apr-19-2024

Expiration Date:
Jun-30-2027

Public Address:
[redacted]

Public City:
Las Vegas

Public State:
Nevada

Public ZIP Code:
89178

Public Country:
United States

Public Phone Number:
[redacted]

Credential:
M.D.

Specialties

Specialty
Radiology, Diagnostic

Education History

Institution	Degree/Certificate	Date Enrolled	Date To
University of California Los Angeles	Bachelor of Science	Sep-01-1989	Dec-17-1993
West Virginia University School of Medicine	Medical Doctor Degree	Sep-01-1997	May-13-2001

Postgraduate Training

Institution	Program Type	Specialty Type	Start Date	End Date
University of California Davis	Internship	Surgery, General	Jun-25-2001	Jun-30-2002
University of Virginia Medical Center	Residency	Radiology, Diagnostic	Jul-01-2003	Jun-30-2007
University of Virginia Medical Center	Fellowship	Radiology, Interventional	Jul-01-2007	Jun-30-2008

Board Actions

Summary	Attachments
None.	

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary	Attachments
None.	

Malpractice Information

Summary	Attachments
None.	

Powered by Thentia Cloud (https://www.thentia.com)

16

16A

State of Nevada

Executive Department

Executive Order 2026-003

Order Requiring a Review of Existing Regulations by All Executive Branch Agencies, Departments, Boards, and Commissions

WHEREAS, *state regulations should protect workers, consumers, and the environment, while promoting entrepreneurship and economic growth; and*

WHEREAS, *state regulations can become outdated, result in unintended consequences, create conflicts, or impose an unnecessary burden on citizens, businesses, or government entities; and*

WHEREAS, *it is in the best interest of the state of Nevada that its regulatory environment be concise, transparent, stable, balanced, predictable, and thoughtfully constructed; and*

WHEREAS, *Nevada's current regulatory structure is too often unfocused and inefficient, contains regulations that are obsolete, and includes regulations that are unnecessarily onerous, thereby limiting the economic potential of the State; and*

WHEREAS, *Executive Order 2023-003 was a critically necessary first step in addressing Nevada's outdated, inefficient regulatory structure by streamlining, clarifying, and reducing over 900 unnecessarily burdensome regulations; and*

WHEREAS, *the continued, thoughtful review of Nevada's regulations should be driven by citizen and industry input, including an initial meeting to garner stakeholder feedback, receive recommendations, and engage in nuanced discussions regarding regulations that should be considered for revision or removal (to improve the general welfare and foster innovation); and*

WHEREAS, *Article 5, Section 1 of the Nevada Constitution provides that, "The Supreme Executive Power of this State shall be vested in a Chief Magistrate who shall be Governor of the State of Nevada;*

NOW, THEREFORE, by the authority vested in me as Governor by the Constitution and laws of the State of Nevada, it is hereby ordered as follows:

SECTION 1:

Every executive branch department, agency, board, and commission shall hold a public hearing, after having provided reasonable notice consistent with Chapter 241 of the Nevada Revised Statutes, to key industry stakeholders, to: (i) solicit from those stakeholders recommendations regarding regulations that should be streamlined, clarified, or removed; (ii) undertake a comprehensive review of the regulations subject to its enforcement; and (iii) identify other regulatory changes the subject department, agency, board, or commission determines worthy of consideration. Any meeting(s) necessary to carry out the directives in this Section must be held no later than October 29, 2026.

SECTION 2:

After receiving the comprehensive stakeholder input described in Section 1, every executive branch department, agency, board, and commission shall substantively review the regulations discussed and/or proposed for revision or removal during those meetings. On or before December 31, 2026, each department, agency, board, and commission shall provide a report to the Governor's office detailing how the regulations subject to its enforcement can be streamlined, clarified, reduced, or otherwise improved to ensure those regulations provide for the general welfare of the State without unnecessarily inhibiting economic growth.

SECTION 3:

As part of its report, every executive branch department, agency, board, and commission shall provide a list of between five (5) and ten (10) regulations recommended for such consideration, ranking them in descending order of priority. Additionally, each report shall include a description of: (i) any recommendations raised by stakeholders; (ii) whether those recommendations were accepted and incorporated into the department's, agency's, board's, or commission's final recommendation; and (iii) if those recommendations were not incorporated, an explanation for that non-incorporation.

SECTION 4:

Reports shall be emailed to the Governor's Office at regreview@gov.nv.gov no later than December 31, 2026. Any questions from any executive branch department, agency, board, or commission regarding reporting obligations should be sent to the same address.

IN WITNESS WHEREOF, I have hereunto set my hand and caused the Great Seal of the State of Nevada to be affixed at the State Capitol in Carson City, this 17th day of August, in the year two thousand twenty-six.

Governor

Secretary of State

Deputy

17

18

Executive Secretary Report

A. Financial Report
B. Issuance of Temporary Licenses and Registrations
C. Change of Address Business List
D. Meetings with Other Health Care Regulatory Boards
E. Licensing Activities Report
F. Citations & Fines issued pursuant to NRS 632.2895
G. Legislative Update
H. 2027 NVBOP Yearly Calendar

September 2026 - Temporary License since last Board Meeting

Pharmacist Name	Pharmacist License #
Tiffany Ogwu	25324
Ian Dettman	25316

Business Name	License #	City, State
LillyDirect Pharmacy, LLC	PH04834	Indianapolis, IN

September 2026 – NV Business Address Change Only

Business Name	License Number	New Location	City, State and Zip
Maxcare Medical Equipment	MP03180	5079 Arville St	Las Vegas, NV 89118

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
Amendment to Nevada Administrative Code (NAC). The proposed amendments establish the minimum staffing standards in a pharmacy and modify the number of pharmaceutical technicians and pharmaceutical technicians in training a pharmacist may supervise.	5/29/24	6/3/24	R113-24	6/25/24 – To Yenh/Dave for review 7/15/24 –sent revised version to Dave/Yenh	12/10/24	1/16/25 – This public hearing was withdrawn from the agenda and will be heard at a future BM. 4/17/25 – To possibly be heard at a future BM.		
Amendment to the Nevada Administrative Code ("NAC") 639. The proposed amendments relate to the licensing requirements for facilities for treatment with narcotics and provide other matters properly relating thereto.	10/17/24	10/21/24	R197-24	7/21/25 – Sent to Dave/Yenh for review.	10/28/25	12/4/25	1/21/26	2/27/26

Amendment to the Nevada Administrative Code ("NAC") 639. The proposed amendments relate to the licensing requirements for facilities for intermediate care or facilities for skilled nursing licensed by the State Board of Health pursuant to NRS 449.0303 and provide other matters properly relating thereto.	12/5/24	12/9/24	R203-24	9/19/25 – Sent to Dave/Yenh for review	10/28/25	12/4/25	1/21/26	2/27/26
Amendment to the Nevada Administrative Code ("NAC") 639.742. The proposed amendments relate to removing the requirement that Dispensing Practitioners must personally dispense at a facility and provide other matters properly relating thereto. The change would allow Dispensing Practitioners to mail prescriptions to individual patients in their care as allowed by the Center for Medicare and Medicaid Services.	12/5/24 – Waiting for the federal reg to pass. The Board would like to see at a future meeting.							
A REGULATION relating to controlled substances adding ethylphenidate and 2-methyl AP-237 to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.	12/5/24	12/9/24	R204-24	7/23/25 – Sent to Dave/Yenh for review	10/28/25	12/4/25	1/21/26	2/27/26

Amendment to Nevada Administrative Code NAC 454. The proposed amendment revises the ability of an advanced emergency medical technicians to possess and administer dangerous drugs upon the order of a practitioner in a license hospital when practicing under their scope of practice as determined by the State of Nevada Health Department.	4/17/25	4/28/25	R004-25	7/22/25 – Sent to Dave/Yenh for review	10/28/25	12/4/25 Note: Agenda item was "A REGULATION relating to the possession and administration of dangerous drugs by an advanced emergency medical technician or paramedic."	1/21/26	2/27/26
Amendment to Nevada Administrative Code (NAC) 639. The proposed amendment specifies the requirements for pharmacies and practitioners to be authorized to engage in the sterile or nonsterile compounding of drug products.	7/17/25	6/30/26	R158-26					

A REGULATION relating to the authority of a homeopathic physician who is not licensed as an allopathic or osteopathic physician in Nevada to possess, administer, prescribe and dispense controlled substances and dangerous drugs; and providing other matters properly relating thereto.	9/4/25 – Tabled and work with Homeopathic Board. 12/4/25	12/9/25	R106-25	1/21/26 – Sent to Dave/Yenh for review	3/17/26	4/16/26	4/22/26	7/1/26
Amendment to Nevada Administrative Code (NAC). The proposed amendments establish standards for licensees relating to staffing, supervision, duties of a pharmacy, duties of a pharmacist and requirements related to the timing of dispensing prescription drugs and devices	9/4/25 – Tabled and make modifications to language. 10/16/25 – Approved with amendments	10/22/25	R072-25	4/1/26 – Sent to Dave/Yenh for review	5/5/26	6/4/26 – Tabled to be heard at a future BM.		
A REGULATION relating to controlled substances adding dipentylone and seven fentanyl related substances to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.	12/4/25	12/9/25	R107-25	12/17/25 – Sent to Dave/Yenh for review	1/28/26	3/5/26	3/19/26	4/29/26

Amendment to Chapter 639 of the Nevada Administrative Code. The proposed amendments reduce the minimum age to register to become a pharmaceutical technician in training along with modify certain requirements to become a pharmaceutical technician in training.	1/15/26	1/20/26	R010-26	2/11/26 – Sent to Dave/Yenh for review	3/17/26	04/16/26	4/22/26	7/1/26
Amendment to Nevada Administrative Code (NAC) 453. The proposed amendments relate to controlled substances adding N-pyrrolidino metonitazene and N-pyrrolidino protonitazene to the controlled substances listed in Schedule I.	3/5/26	3/10/26	R038-26	3/31/26 – Sent to Dave/Yenh & Darla	4/29/26	6/4/26	6/15/26	7/1/26
Amendment to Nevada Administrative Code (NAC) 639. The proposed amendments establishes record keeping requirements of controlled substances by a pharmacy and other matters properly relating thereto.	4/16/26 – Tabled to have further discussion with industry to modify language. 6/4/26 – Tabled to amend language as discussed. 7/16/26	8/5/26	R170-26					

Amendment to Nevada Administrative Code (NAC) 453. The proposed amendments relate to controlled substances adding mitragynine, 7-hydroxymitragynine and mitragynine pseudoindoxyl to the controlled substances listed in Schedule I.	4/16/26	4/29/26	R105-26					
Amendment to Nevada Administrative Code (NAC) 639.708. Regulation authorizing the delivery of a commercially manufactured prescription drug product to a practitioner.	4/16/26	4/29/26	R106-26	5/22/26 – Sent to Dave/Yenh for review.				
Amendment to Nevada Administrative Code (NAC) 639. The proposed amendment requires packaging used to ship prescriptions to contain a device which monitors the temperature of the prescription and alerts the patient if the prescription is exposed to temperatures outside the temperature range listed in the manufacturer's package insert.	6/4/26 - Tabled to amend language as discussed. 7/16/26	7/21/26	R169-26					

Amendment to Nevada Administrative Code (NAC) 639. The proposed amendments relate to the adoption of a fee for the integration of the records of patients in the database of the program established pursuant to NRS 453.162 with the electronic health records of practitioners.	9/3/26 – Awaiting updated WS language from Dave to send to LCB							
Amendment to Nevada Administrative Code (NAC) 639. The proposed amendment clarifies the use of digital identify verification and use of real-time, stop sale system related to products that is a precursor to methamphetamine by a pharmacy and other matters properly relating thereto.	9/3/26	9/29/26	R178-26					

Citations & Fines issued pursuant to NRS 639.2895 (Since last Board Meeting)

- **Cease & Desist/Citation –**
  - **Unlicensed Practice: 4**
  - **Other: 0**

- **Citation & Fine –**
  - **Unlicensed Practice: 1**
  - **Misfill: 0**
  - **Other: 4**

2027
Nevada Board of Pharmacy Calendar

January						
Su	M	Tu	W	Th	F	Sa
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

February						
Su	M	Tu	W	Th	F	Sa
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28						

March						
Su	M	Tu	W	Th	F	Sa
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

April						
Su	M	Tu	W	Th	F	Sa
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

May						
Su	M	Tu	W	Th	F	Sa
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

June						
Su	M	Tu	W	Th	F	Sa
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30			

July						
Su	M	Tu	W	Th	F	Sa
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

August						
Su	M	Tu	W	Th	F	Sa
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

September						
Su	M	Tu	W	Th	F	Sa
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

October						
Su	M	Tu	W	Th	F	Sa
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

November						
Su	M	Tu	W	Th	F	Sa
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

December						
Su	M	Tu	W	Th	F	Sa
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

BOARD MEETING DATES	
Jan 13-14, 20217	Las Vegas, NV - 7830 S Las Vegas Blvd
March 3-4, 2027	Las Vegas, NV - 7830 S Las Vegas Blvd
April 14-15, 2027	Reno, NV - 1790 E Plumb Ln
June 2-3, 2027	Las Vegas, NV - TBD
July 14-15, 2027	Las Vegas, NV - TBD
September 1-2, 2027	Reno, NV - 1790 E Plumb Ln
October 13-14, 2027	Las Vegas, NV - TBD
December 1-2, 2027	Las Vegas, NV - TBD

OBSERVED STATE HOLIDAYS	
Jan 01	New Years Day
Jan 18	Martin Luther King, Jr.'s Birthday
Feb 15	Washington's Birthday
May 31	Memorial Day
Jun 18	Juneteenth Day
Jul 05	Independence Day
Sep 06	Labor Day
Oct 29	Nevada Day
Nov 11	Veterans' Day
Nov 25	Thanksgiving Day
Nov 26	Family Day
Dec 24	Christimas Day

ANNUAL MEETINGS	
APhA Annual	3/19/27-3/22/27 - Charlotte, NC
NACDS Annual	4/18/27-4/20/27 - Palm Beach, FL
NABP Annual	5/11/27-5/14/27 - New Orleans, LA
NASCSA Annual	10/18/27-10/21/27 - Albuquerque, NM
ASHP Mid Year	12/5/27-12/8/27 - Las Vegas, NV
NABP District 8	TBD

19

20

21